

**EXAMINING ISSUES RELATED TO COMPETITION
IN THE PHARMACEUTICAL MARKETPLACE: A
REVIEW OF THE FTC REPORT, GENERIC DRUG
ENTRY PRIOR TO PATENT EXPIRATION**

HEARING
BEFORE THE
SUBCOMMITTEE ON HEALTH
OF THE
COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES
ONE HUNDRED SEVENTH CONGRESS

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EXAMINING ISSUES RELATED TO COMPETITION IN THE PHARMACEUTICAL MARKETPLACE: A REVIEW OF THE FTC REPORT, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION

WEDNESDAY, OCTOBER 9, 2002

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The subcommittee met, pursuant to notice, at 10 a.m., in room 2123, Rayburn House Office Building, Hon. Michael Bilirakis (chairman) presiding.

Members present: Representatives Bilirakis, Upton, Greenwood, Deal, Burr, Ganske, Norwood, Wilson, Pickering, Bryant, Buyer, Pitts, Tauzin (ex officio), Brown, Waxman, Barrett, Towns, Pallone, Eshoo, Stupak, Wynn, Green, and Dingell (ex officio).

Also present: Representative Shimkus.

Staff present: Patrick Morrissey, deputy staff director and counsel; Brent Del Monte, majority counsel; Steve Tilton, health policy coordinator; Eugenia Edwards, legislative clerk; John Ford, minority counsel; and Jessica McNiece, minority staff assistant.

Mr. BILIRAKIS. Shall we please take our seats so that we can get started. Good morning.

I would announce that the opening remarks by the chairman and the ranking member will be for 5 minutes, and remarks from the other members of the subcommittee will be limited to 3 minutes, and I call this meeting to order.

First, I would like to thank our witnesses for appearing before the subcommittee today. The subcommittee values your expertise and we look forward to your expert testimony. I am certain it will help us better understand the issues before us.

The Hatch-Waxman amendments of 1984 established the framework that currently governs the entry of generic pharmaceutical products into the marketplace. The 1984 law attempted to accommodate two important public policy objectives. The first was to speed the entry of lower-cost, generic versions of brand-name drugs into the marketplace. The second, and more subtle, objective was to preserve an environment that encourages companies to develop innovative new pharmaceuticals.

By all accounts, Hatch-Waxman has been a success. Almost half of the prescriptions filled in the United States today are for generic drugs, whereas only 19 percent of prescriptions filled in 1984 were

for generics. However, there are indications that the law needs to be modified to ensure that it continues to meet its original intent.

The Federal Trade Commission recently published an extensive report that identifies certain instances where innovator companies may be using questionable tactics to delay the entry of generic competitors. I am not going to go into the details of the FTC's findings right now or their recommendations. However, suffice it to say that the FTC recommendations could serve as a good starting point for discussions about potential Hatch-Waxman reforms.

I want to emphasize, and members of this subcommittee have heard me say it, I trust, many times, that I have been a long-time supporter of the generic drug industry. Generic drugs are often substantially cheaper than brand-name versions, and we should ensure that American consumers continue to have access to them.

However, I think we must approach Hatch-Waxman reforms cautiously because poorly thought-out, Draconian changes in this area could dramatically reduce the incentive for innovator companies to develop new, lifesaving products. Some of us had a number of entertainers attend our offices last week who have particular illnesses, diseases, and who have asked us to take it slow.

I want to make it perfectly clear that any Hatch-Waxman reforms should not be viewed as a substitute for a meaningful Medicare prescription drug benefit. Although I am disappointed that, once again, my constituents do not have access to a Medicare prescription drug benefit, I am very proud that this committee favorably reported a bill that was subsequently passed by the House.

H.R. 4954, the Medicare Modernization of Prescription Drug Act, is a good bill. It is not a perfect bill. Nobody has ever said it is a perfect bill, but it is a good bill that, if enacted, would help low-income seniors, provide every beneficiary with stop-loss protection, and significantly lower the cost of prescription drugs for all Medicare beneficiaries.

Let me emphasize that last point. Contrary to the rhetoric we hear in this committee, the House-passed Medicare prescription drug bill significantly lowers the cost of prescription drugs. It does so without resorting to an inefficient, government-administered price control scheme.

Instead the bill allows Medicare prescription drug plans to negotiate deep discounts for manufacturers on behalf of Medicare beneficiaries. So every time someone talks about how the House-passed Medicare prescription drug bill does not address the issue of high drug costs, everyone here will know that that claim is absolutely indisputably false.

That said, I believe it is important to carefully review the findings of the FTC report and to hear expert testimony on this matter, and that is why I decided to hold today's hearing. My hope is that members will use this opportunity to ask serious questions about a very complicated subject, and there is no reason why we shouldn't have a thoughtful, measured discussion today.

My fear, however, is that some will, instead, use this opportunity to grandstand and demagogue this issue in an attempt to score some cheap political points. That is unfortunate. We can solve this problem if we work together, if we are not concerned about demagoguery and throwing stones at each other.

I want to thank our witnesses again for taking the time to appear before our subcommittee today. I trust you will provide valuable perspective.

Now I am pleased to yield to the ranking member from Ohio, the gentleman from Ohio, for an opening statement.

Mr. BROWN. Thank you, Mr. Chairman. I appreciate that.

Earlier this year the chairman committed to holding a hearing on Hatch-Waxman reform. I want to thank you, Mr. Chairman, for fulfilling that commitment today. You consistently try to do the right thing. I recognize that and I appreciate that.

If the impact of inflated drug prices on American purchasers were a minor problem or a recent problem, or if prescription drug affordability was a problem unique to seniors, and if we had passed a decent prescription drug benefit in this body, one not written by and for the drug companies, I would not question the majority's decision to hold this hearing just days before Congress adjourns.

But exploding prescription drug inflation is not a minor phenomenon; it is not a recent phenomenon. It is driving up health insurance premiums; we know that. It undercuts the financial security of seniors; we know that. It drains scarce dollars from State and Federal health programs; we know that.

Anti-competitive behavior in the prescription drug market is not a minor or a recent problem either. The FTC has acknowledged it. The Patent Office has acknowledged it. The President has acknowledged it.

Thirty-two State attorneys general and businesses and trade groups and consumer groups and consumer unions throughout the Nation are fighting it, but the problem is statutory. It is something we have a responsibility to fix.

CBO says this anti-competitive gaming, wherein brand and generic drug manufacturers improperly exploit provisions of Hatch-Waxman to block lower-priced competitors from the market will cost American consumers \$60 billion over the next 10 years. If Congress enacts Medicare prescription drug coverage, but doesn't close the loopholes on Hatch-Waxman, the Medicare program and seniors will spend as much as an extra \$100 billion for that coverage over the next decade. This is not a minor problem.

Earlier this summer Mr. Waxman and I asked the majority to work with us to come up with a bipartisan compromise. We were willing to start from scratch, if that is what it took to put a stop to the anti-competitive behavior in the prescription drug market. The majority refused.

I recognize that many on this committee are under tremendous pressure to tow the drug industry's line. No one is ignorant in this body of the close alliance between PhRMA and Republican leadership in the House. No one is ignorant of the close connection and alliance between PhRMA and Republican leadership in the White House. Look at the fundraising; look at the President's appointments; look at the behavior of the new Food and Drug Administration; look at the votes in this House.

But regardless of the majority's allegiance to the drug industry, at some point our inaction on this issue is important to consumers, to seniors, to State governments, to the taxpayers who support Federal and State health programs. At some point our inaction on

this issue, on an issue this important to the American public, is more than irresponsible; it is inhumane.

As you know, there are three bills pending in the House: H.R. 1862, H.R. 5272, H.R. 5311, co-sponsored by scores of Democrats and some courageous Republicans, bills that would address the concerns raised by the FTC report. These bills would help prevent anti-competitive manipulation of the 30-month stay and the 180-day exclusivity provisions of the Hatch-Waxman Act without curtailing the 14 to 17 years of patent protection which drugmakers receive for new products.

In contrast to PhRMA's claim that these bill "threaten medical promise"—by the way, I am not sure if you are familiar with the statement, Mr. Chairman, but it is quoted from the ad PhRMA ran where they counseled parents to pray for a miracle, because if we dare pass S. 812 or one of the bills in the House that I and others are working on, and close loopholes that some, not all, but some drug manufacturers use to cushion their profits, then all research and development will dry up. I will hand out that ad today. I think it is important for all members to see it, so you will know exactly what kind of organization and what kind of demagoguery we are dealing with.

The truth is closing loopholes in Hatch-Waxman would invariably boost medical innovation on behalf of patients like Mr. Barondess from our second panel. Hatch-Waxman loopholes have given drug manufacturers a lucrative alternative, an alternative to innovation. Rather than develop new drugs, they squeeze additional revenues, using expensive attorneys, patent lawyers, and others, out of their old ones. Blocking generic competition to earn a buck doesn't help patients. It hurts innovation and hurts patients.

Let me quote Merck CEO Ray Gilmartin, who runs one of the most profitable companies in America. "We won't engage in any practices simply to delay the arrival of a generic to the market. Extending a patent inappropriately is not beneficial to the consumer or to the health care system because generic drugs play a very important role in keeping down the rate of increase in drug costs. It frees up resources, frankly"—get this—"Generic drugs," CEO Gilmartin says, "Generic drugs free up resources for health plans to be able to afford the new drugs, the breakthrough drugs, not the 'me too' drugs, not the 'gaming the patent system' drugs, but the breakthrough drugs that a company like Merck is bringing to the market."

Mr. Chairman, I appreciate again the opportunity for this hearing. I look forward to talking more about this.

Mr. BILIRAKIS. And I thank the gentleman for his understanding. Three minutes, Mr. Upton.

Mr. UPTON. Thank you, Mr. Chairman.

As we embark on this hearing, let's keep one thing front and center—The 1984 Drug Price Competition and Patent Term Restoration Act is arguably one of the most successful and important health and consumer laws that we have ever enacted. It created this Nation's modern, vibrant generic drug industry. Prior to its passage, generic drug sponsors had to duplicate all of the pioneer

drug sponsors' work, with all the attendant costs in both money and time.

Then generics had about a 19 percent share of the U.S. prescription drug market. Well, since that 1984 law gave them an Abbreviated New Drug Application process and access to the pioneer drug's data and the right to use that data to perfect a copy well before the pioneer's patent has expired, generics' market share has grown rapidly. Today generics have 47 percent of the market, saving consumers \$8 to \$10 billion a year.

At the same time, the 1984 law has provided the pharmaceutical industry with a very effective incentive to invest the many years and hundreds of millions of dollars needed to bring innovative drugs to the market, giving millions of suffering patients hope where once there was little or none.

I am sure that every person here in this room has personally seen, and some have personally experienced, individuals for whom a new drug has literally meant the difference between life and death or a life lived in pain or a life lived with debilitating suffering. I know that all of us who have watched loved ones lose their battle with terrible diseases like cancers, Alzheimer's, ALS, have found ourselves sorely wishing that there were a miracle cure available for them.

The law works because it is balanced. It recognizes—and we need to keep this well in mind, too—that without a vibrant, innovative pioneer drug industry, there can be no generic industry.

I recognize there has been some gamesmanship with the law, and some modifications may be necessary to ensure that generic competition remains healthy. But let's make sure that any cure that we ultimately prescribe is not worse than the disease, and let's fairly evaluate and understand the extent of the problem under current law.

Our Nation leads the world in the development of new drugs that enable us to effectively treat diseases and conditions. But if the incentives are not there to continue new drug discovery and development, and if people cannot afford to buy those drugs, their benefits will be lost to many.

Mr. BILIRAKIS. Please finish up.

Mr. UPTON. How we ultimately address these and other fundamental issues relating to the 1984 law will determine whether we will continue our world leadership in drug innovation and whether patients will have access to the safe, effective, and affordable drugs that they need both now and in the future.

Mr. BILIRAKIS. I apologize to the gentleman.

Mr. UPTON. I yield back the balance of my time.

Mr. BILIRAKIS. He was actually on "caution." Mr. Waxman, 3 minutes, please, for an opening statement.

Mr. WAXMAN. Thank you, Mr. Chairman. I appreciate all the comments that my colleagues have made about the success of this law, which I had an important part to play in its development.

It has been a very successful law, and the idea of the law was to create a balance. We wanted to give incentives for innovation because the consumers of this country and around the world benefit from the investment that leads to new pharmaceutical products to deal with our diseases that otherwise couldn't be addressed.

At the same time, on the other part of the balance we wanted competition. Consumers benefit when there is competition because they can get a better price; they can get a lower price.

We have now seen in recent years—this wasn't a problem in the beginning, but only in recent years—an abuse of the law. I asked the Federal Trade Commission to look at this question and to see if they could determine whether there are tactics that are being used, games being played, by some of the brand-name companies to simply keep competition off the market.

They found that since 1998—the law didn't have this problem from 1984 to 1998, but since 1998 companies have increasingly begun to file multiple late patents, triggering successive 30-month stays of generic competition. This tactic has been used for eight blockbuster drugs, has delayed the availability of generic competition between 4 and 40 months beyond the initial 30-month period.

Moreover, the patents for these particular drugs, when the FTC looked at it, they didn't find that the patent challenges were valid challenges. At the same time they have also found that there is a significant number of collusive agreements between the brand-name companies and the generic manufacturer to keep generics off the market.

They have taken a provision of the Hatch-Waxman law and turned it on its head. The provision was to encourage competition. They have used it to discourage competition, in fact, to stop competition.

We ought to stop the games that are being played, restore the balance that we need in the pharmaceutical area. Let me assure my colleagues and friends that the biggest problem to innovation is with those companies that don't want to invest in new innovative drugs because they want to invest in legal fees to keep competition off the market. If they can continue their monopoly on a product that is a big seller, they don't feel that they need to get new drugs out there, or they are not being successful in getting new drugs developed.

So if we want new drugs for the American people, let's get competition when the patents are through. The law was very, very generous in giving patent protection, the restoration of patent, more exclusive time through GAAP and other means. The patents have even been extended longer through the pediatric bill. We have given an additional 6 months. The companies have plenty of innovative incentives, and we ought to stop the games from occurring.

Mr. BILIRAKIS. I thank the gentleman.

There are four votes on the floor. The Chair will recognize Dr. Ganske for a 2-minute opening statement, and then we are going to break until we have completed those votes.

Mr. GANSKE. I thank you, Mr. Chairman.

We need to pass a Medicare prescription drug bill. We passed one in the House that needs to become law. All across Iowa I have talked to seniors about it. They think that is a very significant improvement in Medicare.

We also need to address the high cost of prescription drugs. We do that in the Medicare bill we passed in the House, but we also need to close some loopholes in the generic law.

There is concern that some brand-name drug manufacturers are preventing generic competition by obtaining multiple 30-month stays. There is concern that there are agreements between brand-names and generics that delay getting those generics onto the market.

That is why I am a co-sponsor of H.R. 5311, the Prescription Drug Affordability Act of 2002, introduced by Representatives John Thune and Jo Ann Emerson. That bill would eliminate the potential for stacked 30-month stays. It would prevent the listing of frivolous patents. It changes market exclusivity rules to prevent collusion between brand and generic drug companies.

Mr. Chairman, I think these are all important changes. I think Mr. Waxman's bill had good intentions, but, like many bills—in fact, maybe most of the bills that we pass here in Congress—after a while you begin to see that you need to do some reform on those bills.

This is a bill that, if we could get it passed, or something equivalent to it, I think it would help bring down the cost of drugs for senior citizens and for everyone in the country. I think that is a laudatory goal.

I appreciate the chairman for having this hearing, and I will yield back.

Mr. BILIRAKIS. I thank the gentleman.

All right, we will break for as long as it takes us, probably 40 minutes, something like that, maybe less than that.

[Brief recess.]

Mr. BILIRAKIS. We will continue with our opening statements, 3-minute opening statements.

Mr. Dingell, for an opening statement.

Mr. DINGELL. Mr. Chairman, I thank you, and I thank you for scheduling this hearing. It is long overdue.

It is at the end of a Congress in which we have sent the distressing message to millions of prescription drug consumers, and that is that the House is content to let the good, bipartisan work of the Senate go to waste.

The Senate has tried to establish an appropriate balance between the legitimate interests of innovator companies and the interests of consumers who stand to benefit from price competition in the marketplace. This body has not. We're past the point of asking whether there is a problem. It is clear when seniors are compelled to choose between paying the rent or buying food to purchase needed prescription pharmaceuticals.

There is a bipartisan agreement on this point, and there are some curious remedies being brought forward, including changing the laws on imports, something which poses significant difficulties to the consuming public and some substantial danger of dangerous pharmaceutical or pseudo-pharmaceuticals being brought into this country.

The administration, which opposed S. 812, the Greater Access to Pharmaceuticals Act, even though it passed the Senate by a wide margin, still says it recognizes that adjustments to current law would improve the fair entry of generic substitutes in the market and prevent future abuses of the patent laws which do occur today.

I would note that we may not all agree with the content of that legislation, but at least serious consideration of it, and allowing the process to go to work to correct the abuses that we find in terms of pricing, is very much in order and very much in the public interest.

Major employers in this country, such as General Motors, are facing unsustainable drug cost increases due to a variety of factors that include costs associated with the delay or denial of generic price competition. I am aware that the answer to their concerns does not rest entirely with generic drugs, but more than \$20 billion worth of prescription pharmaceuticals are due to come off their patent over the next few years. Any unreasonable delay or denial of the market entry of generic drugs has significant implications for the health of our citizens and the health of our country, as well as significant adverse impacts upon American employers.

Mr. Chairman, I want to be as fair as possible in my approach to the subject. I continue to listen to the concerns of drug innovators as well as drug purchasers, but the House appears to be missing a major opportunity, and we are not carrying out our duty to the people in moving forward on this matter. I do not believe that we can hide that unfortunate fact.

Thank you, Mr. Chairman.

Mr. BILIRAKIS. And I thank the gentleman. Mr. Tauzin, chairman of the full committee, for an opening statement.

Chairman TAUZIN. Thank you, Mr. Chairman. Let me express my appreciation to you personally for this hearing to consider the issues surrounding competition in the drug marketplace. As we know, this Nation has, in fact, enjoyed an enormous progress in competition in the drug marketplace because of Hatch-Waxman. Reviewing the problems with the act and also acknowledging its success is an important part of this hearing, I believe.

Without adequate competition, all Americans would pay too much for their drugs, and many do in some cases. At the same time, if we skew the marketplace so much as to allow for immediate competition upon FDA approval of a generic challenging a patented brand drug, it would simply stifle innovation and eliminate the motivation to make those investments. So it is a delicate balance we seek, and I believe today's hearing will help us in seeking the balance and achieving it as quickly as we can.

In 1984, the Congress passed the Hatch-Waxman act, which governs generic drug entry into the marketplace. In exchange for streamlining the generic drug approval process, brand-name drugs had patent life restored, so as to take into account the time lost during the FDA drug approval process. That was the trade: Get generics into the market quicker and at the same time give those who develop and produce new drugs a chance to enjoy the opportunity to recover those investments over the life of their patent, without the patent being used up in time spent at the FDA in approval.

During that time we have seen generics now go up from less than 20 percent of prescriptions filled in the U.S. to nearly half of all prescriptions dispensed. That is remarkable progress. I've got pharmacists in my district, by the way, that are using email and fax technologies now to communicate directly with doctors when a

prescription arrives at their pharmacy, and in those email and fax matrix systems they are setting up doctors can approve generics that they may not have thought about prescribing in the first place.

They tell me they can drive the percentage of prescriptions dispensed with generics even higher than that one-half of the generics dispensed today in prescriptions to as high as 80 percent. That would dramatically, I think, help all of us in this country take advantage of generic drugs, which in many cases are cheaper than brand-names.

At the same time, Hatch-Waxman has allowed companies to continue to innovate, and they spend today roughly \$30 billion per year on research and development. Every one of those new drugs produced and developed is saving lives, extending lives, and making life more bearable for people with illnesses and diseases in this country.

So while we may complain that the act is not working perfectly, I think we will all concede that, I assume all of us would concede that it is working pretty good. I don't expect anyone on these panels to call for us to repeal it. What we are going to hear, hopefully, is how we can improve it. That is why this hearing is good.

Recently, the FTC issued a report examining generic entry in the marketplace prior to the expiration of brand patent rights. The important words to stress here are "prior to the expiration of brand patent rights." The sole focus of that report was whether generics were obtaining access to the market when a brand holds a valid patent issued by the Patent and Trademarks Office. To be sure, some patents may be improperly granted by the PTO, but, according to the FTC, this is not the rule. It has been the exception.

Since passage of Hatch-Waxman, roughly 95 percent of all generics seeking access to the market raise no issue about the validity of the brand patents. That is a pretty high percentage.

With few exceptions, generic access to the market has not been stymied through the system of gaming. There have been exceptions. We ought to correct them.

What the FTC focused upon were eight drugs where brand manufacturers received multiple 30-month stays. At the onset, let me state that I support the notion of the 30-month stay. The 30-month stay allows for a cooling-off period, so tricky patent issues can be litigated. We believe a 30-month stay is appropriate because Hatch-Waxman allows generic manufacturers to commit activities that would otherwise be considered patent infringement prior to generic approval.

So when a person tells me that a brand drug should be treated the same in patent litigation through a requirement that they seek injunctive relief to prevent the FDA from approving the generic, I tell them that that should be the case only if we treat generic manufacturers like all other manufacturers prior to approval. That is, you should not be allowed to infringe upon the front end and then demand to be treated like all the others in the back end.

The question begins, however, and it still lays before us: Is more than one 30-month stay ever legitimate? Truthfully, I don't know that answer. The FTC has studied it and recommends one 30-month stay per drug. I want to hear that reasoning explained to us today.

Further, FTC recommends that when brands settle patent litigation with generics, the FTC should be given notice of the settlement. This, to me, makes abundant sense. I understand the FTC is not calling for approval of the settlement, but rather simple notice. Since anti-competitive settlements do nothing to bring lower-priced generics to the market, this seems like a good starting point for discussion.

Again, Mr. Bilirakis, I want to thank you for calling this hearing.

Finally, let me mention one more thing before we go into the arcane details of Hatch-Waxman. We will hear a great deal of rhetoric today at this hearing about why we must quickly approve the Senate bill, Senate 812, or some similar legislation. Our friends on the other side of the aisle will say that such legislation is sorely needed to bring down the price of prescriptions for seniors. Let me be perfectly clear. The best way to reduce the prices paid by seniors for their prescription drugs is to pass comprehensive prescription drug benefit in Medicare.

The bill we passed through this committee and through the House in June would reduce some seniors' drug spending by well over 50 percent. Approximately 44 percent of Medicare beneficiaries would pay nominal co-pays or no cost-sharing at all. That legislation ought to be signed into law, and it is a shame we are not in conference at this point making that possible for the seniors of America.

As the Energy and Commerce Committee has enjoyed, I believe, a history of great bipartisanship, as we delve into the minutiae of Hatch-Waxman, I hope we can go back to that spirit.

There are some problems in the act. We ought to fix them. There are some things we could do to improve them. But we ought to build on the success of Hatch-Waxman, and we ought to build on it as Americans, not as Democrats or Republicans. I hope as we learn about these important issues today, this committee will begin to see its way clear to doing that.

Thank you, Mr. Chairman.

[The prepared statement of Hon. W.J. "Billy" Tauzin follows:]

PREPARED STATEMENT OF HON. W.J. "BILLY" TAUZIN, CHAIRMAN, COMMITTEE ON
ENERGY AND COMMERCE

Mr. Chairman: I appreciate you holding this hearing to consider the issues surrounding competition in the drug marketplace. As a Congress and as a nation, we must ensure that competition in the drug marketplace remains vibrant. Without adequate competition, all Americans would pay too much for their drugs. At the same time, if we skew the marketplace so much as to allow for immediate competition upon FDA approval, we would stifle innovation. So it's a delicate balance we seek, and I believe today's hearing will help us in seeking that balance.

In 1984, the Congress passed the Hatch-Waxman Act, which governs generic drug entry into the marketplace. In exchange for streamlining the generic drug approval process, brand name drugs had patent life restored so as to take into account the time lost during the FDA drug approval process. Since the Act was passed, we have seen generics go from less than 20% of the prescriptions filled in the United States, to nearly half of all prescriptions dispensed. At the same time, the brands continue to innovate, spending roughly \$30 billion per year on research and development. So while some may complain the Act is not working perfectly, I assume all would concede that it's working pretty well. Certainly, I do not expect to hear anyone call for a repeal of the Act.

Recently, the FTC issued a report examining generic entry into the market prior to the expiration of brand patent rights. The important words to stress here are "prior to the expiration of brand patent rights." The sole focus of the report was

whether generics were obtaining access to the market when a brand holds a valid patent issued by the Patent and Trademark Office. To be sure, some patents may be improperly granted by the PTO. But, according to the FTC, this is not the rule, but rather the exception. Since passage of Hatch-Waxman, roughly 95% of all generics seeking access to the market raised no issue about the validity of brand patents. With few exceptions, generic access to the market has not been stymied through a system of gaming.

What the FTC focused upon were 8 drugs where brand manufacturers received multiple 30-month stays. At the outset, let me state that I support the notion of a 30-month stay. A 30-month stay allows for a cooling off period so that tricky patent issues can be litigated. We believe that a 30-month stay is appropriate because Hatch-Waxman allows generic manufacturers to commit activities that would otherwise be considered patent infringement prior to generic approval. So when a person tells me that brand drugs should be treated the same in patent litigation, through a requirement that they seek injunctive relief to keep the FDA from approving the generic, I tell them that should be the case only if we treat generic manufacturers like all other manufacturers prior to approval. That is, you should not be allowed to infringe on the front end and then demand to be treated like all others on the back end.

The question becomes, however, "Is more than one 30-month stay ever legitimate?" Truthfully, I don't know the answer. The FTC has studied this issue very carefully, and recommends one 30-month stay per drug. I want to hear this reasoning explained to me today.

Further, the FTC recommends that when brands settle patent litigation with generics, the FTC should be given notice of the settlement. This, to me, may be sensible. I understand that FTC is not calling for approval of the settlement, but rather a simple notice. Since anti-competitive settlements do nothing to bring lower-priced generics to the market, this seems like a good starting point for discussion.

Again, Chairman Bilirakis, I appreciate you calling this hearing on this very important topic. While it's easy to say we must rush to reform Hatch-Waxman, the one thing we cannot do is reform it in a way which threatens innovation. Without innovation, patients are harmed. Without innovation, research moves overseas. Without innovation, there is no generic pharmaceutical industry. Let us always remember: Hatch-Waxman has worked very well. If reforms are needed, we must draft these reforms correctly.

Finally, let me mention one more thing before we go into the arcane details of the Hatch/Waxman Act. You will hear a great deal of rhetoric at this hearing about why we must quickly approve S. 812 or some other similar legislation. Our friends on the other side of the aisle will say that such legislation is sorely needed to bring down the price of prescriptions for seniors.

Let me be perfectly clear. The best way to reduce the prices paid by seniors for their prescription drugs is to pass a comprehensive prescription drug benefit in Medicare. The bill we passed through the House in June will reduce some seniors drug spending by well over 50%. Approximately, 44% of Medicare beneficiaries will pay only nominal co-pays and no cost-sharing. That's legislation that should be signed into law right away.

At the Energy and Commerce Committee, we have a proud history of bipartisan-ship. As our Committee delves into the minutia of Hatch/Waxman, I hope that we do so in the spirit of that finest bipartisan tradition and examine this law on the merits. We have many important issues before us today. Let both sides approach them with an open mind and a willingness to be educated.

Mr. BILIRAKIS. Thank you. I thank you for the wisdom of your remarks, Mr. Chairman, and would yield 3 minutes to Mr. Pallone for an opening statement.

Mr. PALLONE. Thank you. Let me say that I very much disagree with what the chairman of the full committee just said about what we should be doing and what the other body should be doing. I mean, the bottom line is that this generic Greater Access to Affordability Pharmaceuticals Act, the bill that passed the Senate, is really the only game in town.

As much as I am happy that we are having this hearing today, we need to pass a generic bill. We need to make the changes to Hatch-Waxman and pass the Senate bill. The fact that we are hav-

ing a hearing is not enough. The subcommittee, the full committee should be marking up the Senate bill.

I am all for a Medicare prescription drug benefit, but the bottom line is that that is not going to happen. This can happen very easily if this committee would just take the bull by the horns and do what has to be done.

Keep in mind also that the Medicare benefit, although it is a great thing, doesn't address costs. The Republican bill doesn't address cost. It only deals with senior citizens. If you pass the Senate generic bill, the Hatch-Waxman reform, it would lower costs for all Americans, not just for senior citizens.

I think the Republican leadership on the committee, basically, what they are doing is they are saying, look, we know there are all these problems with Hatch-Waxman. The FTC report shows dramatically that the brand-name industry is causing the problem and causing all these delays for generics. Yet, they are not willing to bring it up.

Why not? Well, the reason is simple: because the brand-name industry is financing campaigns. They are running ads for all the Republican candidates in the competitive districts telling them that you should vote Republican.

You know, the brand-name industry is the problem here, and the Republican leadership on this committee is not willing to address the problem because they want the help that they are getting from the brand-name drug companies in their campaigns and in these competitive races. That is what this is all about.

We don't need a hearing. We need to pass a bill and we need to deal with the issue of cost. The Republican bill, even the Medicare benefit bill, doesn't deal with the cost issue. I have mentioned many times in this committee about the non-interference clause that is in the Republican prescription drug bill that specifically says that the person in charge of the program cannot essentially negotiate price reductions. That is what the bill says because that is what the brand-name industry wanted. They don't want us to deal with the cost issue. They don't want more generics brought to the market.

I mean this FTC report unambiguously confirms that Hatch-Waxman is being abused. It details that brand-name companies are manipulating the approval process. They are the problem. These additional 30-month stays are being triggered by the strategic submission of inappropriate patents by the brand-name drug companies, listings in the FDA's "Orange Book," and they go on to talk about the other problems with the 180 days. I mean, we don't need anything more.

The subject of this hearing clearly shows in this FTC report that the brand-name industry is abusing the system. Let's do something about it. Don't just keep talking.

Thank you, Mr. Chairman.

Mr. BILIRAKIS. The gentleman's time has expired. Mr. Shimkus, opening statement, 3 minutes.

Mr. SHIMKUS. Thank you, Mr. Chairman. I ask unanimous consent that the testimony of the Coalition for a Competitive Pharmaceutical Market be submitted for the record.

Mr. BILIRAKIS. Without objection.

[The prepared statement of the Coalition for a Competitive Pharmaceutical Market follows:]

PREPARED STATEMENT OF COALITION FOR A COMPETITIVE PHARMACEUTICAL MARKET

Chairman Bilirakis, Congressman Brown, and distinguished Subcommittee members, the Coalition for a Competitive Pharmaceutical Market (CCPM) commends the Subcommittee for its leadership in addressing the critical issue of improving consumer access to affordable generic drugs in light of unsustainable increases in the cost of prescription drugs. On behalf of our members, we appreciate this opportunity to submit written comments to the Subcommittee.

CCPM is an organization of large national employers, insurers, generic drug manufacturers, and others committed to improving consumer access to high quality generic drugs and restoring a vigorous, competitive prescription drug market. CCPM supports legislation to eliminate legal barriers to timely access to less costly, equally effective generic drugs.

Our membership is broad and diverse, and includes numerous prominent purchasers of pharmaceuticals, such as General Motors Corporation, Caterpillar, Inc., Eastman Kodak Company, and Delphi Corporation. We are eager to share with the Subcommittee our experience regarding prescription drug cost increases and to underscore our belief that the House of Representatives needs to act now to eliminate legal barriers to timely access to affordable, equally effective generic drugs by passing H.R. 5311/H.R. 5272.

IMPACT OF UNSUSTAINABLE PRESCRIPTION DRUG COSTS

Large and small businesses, consumers, unions, governors, the federal government and health plans throughout the nation are aggressively attempting to manage soaring prescription drug costs. These expenditures are growing at annual rates of up to 20 percent and are unsustainable. Current pharmaceutical cost trends are increasing premiums, raising copayments, pressuring reductions in benefits, and undermining the ability of businesses to compete. CCPM members seeking to continue to provide prescription drug coverage to employees and subscribers face a tremendous challenge in light of these skyrocketing pharmaceutical costs.

For example, General Motors—the largest private provider of health care coverage in the nation, insuring over 1.2 million workers, retirees, and their families—currently spends over \$1.3 billion a year on prescription drugs. Despite GM's use of state of the art management techniques that assure the most appropriate and cost effective use of prescription drugs, its pharmaceutical bill continues to grow at a rate of 15 to 20 percent a year—more than quadrupling the general inflation rate.

Similarly, Eastman Kodak Company, which insures 150,000 covered lives, spends 31 percent of its health care dollar on prescription drugs. Kodak is on track to spend \$88 million on prescription drugs this year, and estimates that their drug costs will increase to at least \$99 million in 2003.

Likewise, equipment manufacturer Caterpillar Inc. spent \$131 million on prescription drugs last year, representing a 17 percent increase over the previous year. Moreover, Caterpillar has experienced drug cost increases ranging from 17 to 25 percent over the past five years.

The experience of insurers is no different. The 42 Blue Cross and Blue Shield Plans that collectively provide health care coverage for 84.4 million Americans, represented in CCPM by the Blue Cross and Blue Shield Association (BCBSA), are experiencing up to 20 percent increases in prescription drug costs each year. BCBSA expects these costs to continue to grow rapidly, exacerbating the difficulty of providing a meaningful level of coverage for prescription drugs while keeping premiums as affordable as possible.

Such drug cost increases are driven by multiple factors, including higher utilization, direct-to-consumer advertisements, drug price increases, and, especially, delayed generic competition.

CCPM members are growing increasingly concerned that a major contributor to the pharmaceutical cost crisis is the use of the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman) in ways clearly unanticipated by Congress and which effectively block generic entry into the marketplace. We believe that inappropriate Orange Book patent listings, the repeated use of the 30-month generic drug marketing prohibition provision and other legal barriers have resulted in increasingly unpredictable and unaffordable pharmaceutical cost increases.

GENERIC DRUGS PROVIDE CRITICAL COST SAVINGS

Every day, the choice of generic products creates substantial savings for consumers; as much as 70 to 80 percent when compared to the brand product. This adds up to more than \$10 billion dollars a year in savings for consumers, employers, insurers, and taxpayers, as well as state and federal governments. Generic drugs play a critical role in the search for answers about how to decrease health care costs, while increasing access to important medicines and assuring health care coverage availability.

Like their brand-name counterparts, generic drugs are subject to thorough review by the Food and Drug Administration (FDA) to ensure that they are safe and effective. The generic manufacturer relies on the underlying safety and efficacy data supplied by the brand manufacturer when it submits its application to the FDA for approval. In addition, the generic manufacturer must demonstrate in its application that the generic drug is equivalent to the branded product based on bioavailability and/or bioequivalence studies to win FDA approval.

LEGAL BARRIERS TO GENERIC ACCESS IMPEDE VIGOROUS MARKET COMPETITION

Generic drugs offer consumers a safe, equally effective and affordable alternative to brand name prescription drugs. However, the lack of access to high quality generic drug choices for Americans leads to increased premiums, higher co-payments, fewer health benefits, and reduced access to quality care—particularly for the uninsured and poorly insured.

CCPM commends the Subcommittee for focusing today on barriers to generic entry into the marketplace. We believe, and the recent report from the Federal Trade Commission “Generic Drug Entry Prior to Patent Expiration” confirms, that such barriers have cost consumers billions in lost savings and will continue to do so absent swift legislative action. Without relief from rising prescription drug costs, employers and other purchasers simply will be unable to effectively compete in the world marketplace.

Specifically, such legislation should:

- End delays associated with the automatic 30-month stay;
- Accelerate generic drug introduction to market; and
- Expedite resolution of patent disputes.

End Delays Associated with the Automatic 30-Month Stay

A brand name drug manufacturer can delay generic competition for 30 months because current law requires the FDA automatically to stay approval of a generic application if the brand manufacturer sues for patent infringement. In fact, current law allows multiple, automatic 30-month stays, further delaying market entry for generic drugs. Restricting the availability of the automatic 30-month stay would still permit brand manufacturers to sue generic companies. However, like patent holders in all other industries, brand manufacturers would have to obtain a preliminary injunction based on merit to delay generic drug approvals.

For example, the manufacturer of Neurontin® strategically timed the submission of an additional patent to FDA, effectively converting the automatic 30-month stay into a 54-month delay of generic competition. The cost in lost savings to consumers has already amounted to well over \$825 million. With each new day the public loses an additional \$1.5 million.

Accelerate Generic Drug Introduction to Market

Current law grants a 180-day period of market exclusivity to a generic applicant who first files an application with the FDA certifying that the patents on the brand product it intends to copy are either invalid or will not be infringed by the manufacturing and marketing of a generic version of the drug. However, the 180-day period does not begin until the first applicant goes to market or litigation surrounding the certification is resolved. In the interim, all other generic applicants are kept out of the market.

The 180-day exclusivity provision now available to the first generic challenger should be available to a subsequent challenger, if the initial challenger does not go to market within a specified period or the FTC finds the applicant engaged in unlawful conduct (such as an agreement with a brand manufacturer to stay out of the market).

Additionally, a Federal appellate court decision, or the date of a settlement agreement or consent decree that includes a finding of invalidity or noninfringement should be designated as “triggers” for the 180-day period to provide certainty for the generic applicant.

Expedite Resolution of Patent Disputes

A brand manufacturer enjoys a statutory 45-day window during which it may file an infringement suit against a generic challenger and obtain an automatic 30-month stay. Under current law, a generic manufacturer must wait to be sued and complete litigation to achieve certainty of its right to market its product—or risk triple damages if it markets an approved generic drug while a suit is pending. Generic manufacturers should be permitted to challenge patents inappropriately listed with the FDA, with a correction or de-listing remedy available. This statutory change would reduce the amount of litigation surrounding drug patents and expedite consumer access to affordable medicines.

COST IMPACT ON CCPM MEMBERS

In addition to the well-documented cost savings that generic drugs provide, there is ample data on the lost savings to consumers when generic drug access is delayed. For example, the Congressional Budget Office (CBO) examined a bill passed by the Senate in July 2002 (S. 812) that would eliminate many of the barriers to generic drug market entry discussed above. CBO concluded that consumer savings generated from such legislation could reach as much as \$60 billion over the next ten years. CBO further determined that if all barriers to generic drug market entry were eliminated, the total savings could reach \$120 billion over 10 years.

CCPM member Eastman Kodak estimates that approximately one-third of its current expenditures on prescription drugs is spent on brand name drugs for which generic counterparts are expected to be available in the near future. Similarly, Caterpillar anticipates that if generic competition is introduced for the 15 most popular drugs expected to go off patent by 2006, it will save between \$25 to \$30 million per year.

General Motors estimates that without new legislation, if just five pharmaceutical “blockbuster” product patents that are currently scheduled to expire are extended, GM will see increases in its prescription drug bill in excess of \$204 million during the period of delay of generic market entry.

SUPPORT FOR BIPARTISAN LEGISLATION TO IMPROVE ACCESS TO GENERIC DRUGS

In light of the unintended consequences of Hatch-Waxman provisions that serve to impede access to safe, affordable generic drugs, CCPM believes that Congress must act now to pass legislation that will restore the balance between competition and innovation that was initially intended by the Congress in 1984. Specifically, CCPM supports the Prescription Drug Affordability Act (H.R. 5311) and the Prescription Drug Fair Competition Act (H.R. 5272).

Last week, CCPM joined with the RxHealth Value coalition and AARP in releasing a new AARP survey that found overwhelming support for legislation to close loopholes used by some pharmaceutical companies to prevent generic drugs from being made available to consumers. As the largest consumer group in the nation, AARP supports the House bills because, according to its survey, the vast majority (92 percent) of Americans age 45 and older is concerned about the impact of rising drug costs on their health care coverage.

In addition, the AARP survey revealed that 84 percent of older Americans strongly believe that making generic drugs more available is an important part of the solution to rapidly increasing drug prices and two-thirds support legislation to make generic drugs more available.

It is important to note that nothing in the legislation introduced by Representatives Waxman and Brown, or Representatives Thune and Emerson, diminishes the patent rights of brand-name pharmaceutical manufacturers. The legislation does not in any way amend Title 35 of the U.S. Code, which protects the patents of all manufacturers, including CCPM members. As innovators, patent-holders and competitors in the world market, CCPM members respect the integrity and value of intellectual property protection. However, we oppose practices that detract from true innovation and new product development and merely serve to preserve of old innovations.

CONCLUSION

CCPM applauds the Subcommittee and the FTC for examining the critical health care issue of assuring continued access to safe, affordable generic prescription drugs.

CCPM believes that Hatch-Waxman reforms—such as the Prescription Drug Affordability Act (H.R. 5311) and the Prescription Drug Fair Competition Act (H.R. 5272)—can enhance competition and choice while also encouraging meaningful innovation. The Senate recognized as much when it passed similar legislation in July 2002 by an overwhelming bipartisan vote of 78-21. CCPM maintains its commit-

ment and support for the Congress to pass this legislation this year; delay would mean yet another year of excessive prescription drug costs that create pressures that make it more difficult for businesses to compete and health plans to offer affordable, meaningful insurance.

Mr. Chairman, we appreciate your leadership in holding this hearing. We look forward to working with you and providing any assistance possible in developing legislation in this area.

Mr. SHIMKUS. Thank you, Mr. Chairman, and I will be brief.

First of all, this does address a cost issue across the country on prescription drugs, but I would remind my friends and Mr. Pallone, who just talked, that under the prescription drug bill many of you voted against the best pricing provision that the VA uses that would have saved \$19 billion. That was a way in which, through passing that—so there was cost-benefit provisions in our prescription drug bill. The best pricing is what the VA uses. That is why we have been able to expand—

Mr. PALLONE. Will the gentleman yield?

Mr. SHIMKUS. Yes, I will be happy to yield.

Mr. PALLONE. I don't know—if you are talking about trying to use the VA—

Mr. SHIMKUS. Model.

Mr. PALLONE. [continuing] model, I know that—

Mr. SHIMKUS. You all voted against it.

Mr. PALLONE. We supported that.

Mr. SHIMKUS. No.

Mr. PALLONE. Mr. Stupak—

Mr. SHIMKUS. In the amendments, the best pricing model.

Mr. PALLONE. It was Mr. Stupak's amendment, and we voted for it.

Mr. SHIMKUS. There was \$19 billion in savings in this bill. So to say that our prescription bill doesn't have price savings is wrong.

Mr. PALLONE. You have a non-interference clause in the bill that specifically says that the administrator of the program cannot negotiate—

Mr. SHIMKUS. Reclaiming my time—

Mr. BILIRAKIS. Gentlemen, this is an opening statement. The gentleman has the time.

Mr. SHIMKUS. Reclaiming my time, I would just say that \$19 billion is a significant savings to the senior citizens for prescription drug benefits, and that was passed in our bill.

I would also respond and concur with the chairman, who said the real question is, is one 30-month stay legitimate? That is the basic premise of the FTC report. That is what we are going to hear today.

As many of the folks who are here know, we want to hear the testimony to make the case of reforms needed to make sure that we get low-cost prescription drugs and that we continue innovation and development, because innovation and development is only occurring here in the United States today because of our ability and our patent protections.

So this is an important hearing. I thank the chairman for having the hearing and Chairman Tauzin for allowing us to have this, period, and I yield back my time.

Mr. BILIRAKIS. And I thank the gentleman. Mr. Stupak, for an opening statement, 3 minutes.

Mr. STUPAK. Thank you, Mr. Chairman, and thank you for holding this hearing on competition on the prescription drug market.

Last year prescription drug spending increased by \$20.8 billion or 18.8 percent. Seniors, one-third of whom lack prescription drug coverage, received a 2.4 percent cost-of-living increase in their Social Security benefit last year. Simply put, the math just does not add up.

This is not just about seniors, but all Americans cannot afford double-digit increases in costs each year for their pharmaceuticals. Something needs to be done.

Let me be clear on one important point. I'm not blindly pro-generic; I'm pro-competition because competition has proven to be the great marketplace equalizer.

Our hearing today was triggered by a report released in early August by the Federal Trade Commission, the FTC. The results of this report concluded that there were certain abuses of the Waxman-Hatch generic drug legislation and that legislative fixes are needed to close these loopholes that prevent generics from coming swiftly to the market.

Legislative fixes are certainly needed, especially when States are now being sued for trying to keep down prescription drug costs by incorporating generics into their Medicaid formulas. My home State of Michigan is attempting to limit out-of-control drug costs in this way and is being sued by PhRMA to prevent this from happening.

PhRMA reasoning is this, and I quote: "Our argument is, why would you want to put this in place when you're going to hurt some of the most vulnerable people in Society?" That is attributed to John Brown, PhRMA State lobbyist.

PhRMA apparently sees no irony in this statement while I do. This same PhRMA spokesman goes on to say that States shouldn't balance budgets on the backs of poor. I find it ironic and sad that they are willing to hurt these vulnerable people by forcing them to pay top dollar for drugs they cannot afford while using this same vulnerable populations as cover to ensure their financial bottom line, to make sure that their bottom line is the healthiest in the country.

PhRMA's claim that the Senate-passed generics bill, S. 812, will chill innovation and we won't have new therapies, again, just the opposite is true. By closing the loopholes in the Waxman-Hatch, the brand industry will be able to go back to the lab to come up with new medicines to make money, instead of pouring financial resources into how best to use legal loopholes so as to make their money stretch out to protect their monopolies.

They can also do it by reducing their advertising. They spend twice as much money on advertising than they do on development of new drugs. These abuses, outlined in the FTC report, are serious and cost the health care system billions of dollars in inflated drug costs.

In closing, let me say that a solution to these abuses exists and has been passed overwhelmingly by bipartisan support in the Senate of 78 to 21. A broad range of groups—employers, insurance, consumers, labor, Governors—support congressional action. We should respond to their requests and to our constituents' requests

for action to lower drug costs and follow the Senate's lead by passing our companion bill to S. 812 and pass it this year.

With that, Mr. Chairman, I yield back my time.

Mr. BILIRAKIS. I thank the gentleman. Dr. Norwood, for an opening statement.

Mr. NORWOOD. Thank you, Mr. Chairman. I appreciate you holding this hearing on what I consider to be a very complicated subject.

I can't help but note that my friend, Mr. Pallone, doesn't agree with the chairman, and I would like to say that I could associate myself with his remarks real well. Though I am not certain where I want to be yet, I have had people, as all of us have, coming in and out of our office every day; one side saying, "We're right and the other side's wrong," and the other side saying, "No, we're right." It's been back and forth now for a while on this generic drugs and the Hatch-Waxman amendment. I am not totally certain where I need to be, but I am absolutely certain that neither side is completely right and neither side is completely wrong.

This is a very important issue because the cost of drugs is a driving factor in so much of health care today. For seniors, it is the force behind our efforts to pass a prescription drug bill, and for our employers and insurers, it is a driving force behind premium increases.

Getting generic competition in the market is clearly in the public interest. Are there loopholes in Hatch-Waxman that need to be fixed? I believe the FTC was right in outlining certain areas of current or potential abuse in S. 812 or the Brown bill, but the answers to these concerns, is that the answer? I am not sure I believe so. I think they probably go a little too far.

But one thing I am certain of is that the Hatch-Waxman bill has worked. We have increased generics in this country over the last 20 years from 20 percent of the market to 50 percent of the market. The brands have done a great job in their R&D. They have increased that by \$30 billion.

I think it would be an interesting question for us to answer, well, what would happen if generics had 75 percent of the market? What would happen to prescription drugs in this country if they had 95 percent of the market? Is that a good idea?

Is the bill working perfectly? No, we need to fix some of the areas of political abuse, but I think we should be cautious, very cautious, before we dive head-long into tinkering with a law that has actually worked pretty well.

I also want to mention that, even though we don't want to embarrass the Senate because they have put out a bill, and there hasn't been many, so the very little work they have done, we may not want to waste. But I would say to them also that we put out a bill, too, that helped senior citizens a lot, and that is the prescription drug bill, and they need to deal with the fact that our poorest seniors and our sickest seniors should be dealt with with a prescription drug bill. So I am not sure exactly which issue we should be on. Just because the Senate says it is dead, I am not sure we need not tell them their issue is dead, too, until they can learn to play.

Mr. Chairman, I look forward to this testimony of our witnesses today. I view this as a great opportunity for learning and listening. We will see where we need to be, but I tend to agree with the chairman again: Perhaps the Senate bill is just not exactly what the House wants. We usually can come up with a little better solution, and we need to have our own.

Thank you, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman. Ms. Eshoo, for an opening statement.

Ms. ESHOO. Good morning, Mr. Chairman, and thank you for having this hearing today. It is an important one because it is a very important issue for the American people.

Being almost the last one to make an opening statement, I would like to make just a couple of observations that I didn't have part of my written copy. That is to say that I think that it is safe and sad to say that a prescription drug bill is not going to be passed by the Congress. We are going to be taking a vote on war tomorrow. The statements will be completed on the floor very shortly.

As we talk about competition, here in the House of Representatives my friends on the other side of the aisle don't believe in the competition of ideas. When you talk about a prescription drug bill, you wouldn't allow another idea to be brought to the floor to be debated. That is wrong. That is wrong.

This business about the Senate, I am sick and tired of it. The Senate, whether you like the bill or not, passed almost 100-to-nothing. So it is the responsibility of the House to not only have a hearing at 2 minutes until midnight before we leave to go home for the mid-term elections, but to have had a markup here. I may not agree with everyone here about the innards of the Senate bill, but we have a responsibility to come up with something and, most frankly, we are not going to.

I look forward to the distinguished people who are here to testify today because, if I am blessed enough to come back in the 108th Congress, we have to use your wisdom on what direction we need to go.

Hatch-Waxman has been successful, but we know many years later that there are some abuses and that we need to straighten that out. Why? Because it creates an opportunity for the American people to not only benefit from generics, but also from the investments that are made in this country relative to drugs. So we need to keep innovation going, and we need to protect what the American people, especially the poor, the elderly, and those that are uninsured, benefit from.

So there are abuses. We need to correct them, but let's not suggest at this very important hearing that the Congress of the United States is going to be taking care of this forthwith. Let's not be posing for "holy card" pictures because it is not going to be done. This is being brought up, as I said, just a few minutes before midnight before Paul Revere rides out of town.

I know that our chairman always wants to do the right thing, and I appreciate that. He is a gentleman. He is a decent person, and I will always stand with that. But the tenor and the exaggeration that is here today on the part of some of my colleagues really does not befit a very distinguished committee and where we are in

the last throes of a Congress that is debating war, and not passing either a bill to make the corrections that need to be made or a Medicare prescription drug benefit that actually is in Medicare. We can debate that.

Mr. BILIRAKIS. The gentlelady's time has expired.

Ms. ESHOO. I thank the chairman.

Mr. BILIRAKIS. I thank the gentlelady. Mr. Pitts, for an opening statement.

Mr. PITTS. Thank you, Mr. Chairman. Thank you for holding this important hearing today. I look forward to hearing about the state of competition between brand and generic drugs and whether improvements in this marketplace are necessary.

Mr. Chairman, it has been said this is probably one of the more complicated issues the subcommittee has dealt with to date. I believe this hearing will allow all of us to get a better picture of the industry.

I think it is important to note that the numbers show that Hatch-Waxman has been generally successful. It has maintained the balance of improving the generic drug approval process while at the same time providing patent term restoration to the brand drug industry. As we all know, a competitive market for the pharmaceutical industry relies on new innovation. I believe we have a responsibility not to hinder this innovation.

That said, I am aware of the concern that some have expressed that generic drug approvals have been unnecessarily delayed due to patent listings. So I believe this hearing will be an excellent opportunity to examine these concerns. We need to know whether the reforms identified within the FTC report are appropriate. We need to know what the impact of the recommended FTC reforms may have on brand-name drug innovation.

I will submit my entire remarks for the record, but say, in conclusion, Mr. Chairman, I look forward to hearing from our distinguished witnesses and yield back the balance of my time.

Mr. BILIRAKIS. I thank the gentleman for his consideration. Mr. Green, for an opening statement.

Mr. GREEN. Thank you, Mr. Chairman. I would like to join my colleagues in expressing regret that I think a lot of discussion on this bill would have been taken care of if we had actually been able to consider alternatives on the floor of the House to our committee product that took us all night.

Although this bill, the bill we are holding hearings on, I appreciate, again even at this late date, the hearing on changes in the Drug Price Competition and Patent Term Restoration Act, also known as Waxman-Hatch, prescription drugs are a central part of our health care system, and advances in the area of pharmaceutical research have led to new treatments for diseases such as AIDS, diabetes, cancer, arthritis, and dozens of others.

Although there is no doubt that we should do all we can to ensure that that kind of innovation continues, the cost of these drugs remains a concern to all Americans, but particularly our elderly. Health care costs rose 5 percent in 2001, 3.7 times faster than the overall inflation rate, this in large part due to the increase in the cost of prescription drugs.

Prescription drug cost spending is the fastest-growing component of health care costs and rose 17 percent in 2001. This increase has a ripple effect not only in the private sector, health insurance, State Medicaid programs, employers, uninsured, and seniors, but also in our Veterans' Administration health care programs.

Congress tried to balance two conflicting interests when they passed Waxman-Hatch in 1984, and there is no question it is an extremely complex and challenging area of FDA law. It has been successful. In our committee memo it says that generic drugs have risen from 40 percent to 50 percent of all prescription drugs dispensed. At the same time, brand innovation and the research and development has increased to nearly \$30 billion.

Unfortunately, with these improvements have come new loopholes that have created the opportunity for abuse in our current system. Innovator companies often file a number of patent, staggering patent applications, to extend the patent protections and, thus, their market exclusivity.

Each time an innovator lists a new patent, generic companies must file for a paragraph (IV) certification, which triggers an automatic 30-month stay before the FDA can approve their product. By staggering new patents, this loophole creates the possibility of innovator companies to receive multiple and unlimited stays on a single drug. The patent stacking results in lengthy delays.

Additionally, these new patents are often for secondary changes, such as the pharmaceutical's color, labeling, or expiration date. These kinds of minor changes are not the innovations that Congress sought in the Waxman-Hatch bill.

Additionally, the 180-month stay provision which was intended to promote generic competition has been abused by some generic companies who have colluded with their brand-name counterparts to keep lower generics off the market. There have been several pieces of legislation introduced to address these abuses, and Americans need timely access to affordable medications.

Senate bill 812 would contain many of the provisions. Again, I don't think you would see as much support for this bill if we had considered and passed a real prescription drug benefit under Medicare.

I yield back my time.

Mr. BILIRAKIS. I thank the gentleman. Ms. Wilson, for an opening statement.

Mrs. WILSON. Thank you, Mr. Chairman. I also appreciate your having this hearing because I think it is a beginning of a very important process of considering what we have to do to improve and build upon the Hatch-Waxman bill, and that is kind of a big deal. I don't think it is easy, and I think the idea that we could quickly pass this bill is probably not true. I think there will be people who want to look at a lot of the different provisions of Hatch-Waxman, and we need to consider how we are going to do that.

I come to this with the perspective of a consumer and a former small business owner, but the real issue is, what is the price to the consumer and whether small businesses, particularly, can continue to offer health insurance to their employees. It is now not even an issue so much for small business as medium-sized business and

large business, where health insurance premiums continue to go up.

I don't believe that there is a single-point solution to this problem. I don't think there is an "only game in town," not in this town and not in the town that I live in.

We need to add a prescription drug benefit to Medicare. We passed a plan through this House. I wish that the Senate had been able to pass one and we could come together in conference and get that done. We are going to have to come back and do it again in the next Congress, and I will be there to try to craft the best bill possible for our consumers and our seniors.

I think we need to consider allowing the importation of safe prescription medicines that are made in FDA-approved facilities, and I think that that will put a little back pressure on the pharmaceutical companies, because, frankly, the difference between the cost of medicine in Juarez and the cost of the same medicine in Albuquerque is too big. It causes people to be traveling to Mexico to buy medicine.

I drink my orange juice that may come from Mexico. It seems to me that we should be able to figure out a way to get safe medicine from other countries.

We need to look at the generic medicine law, and that is what this hearing is about; both the 30-month stay and things like the difference in price is substantial. I think we need to look at that law.

I think we need to also protect the motivation for innovation. You know, if we want to just freeze the prescription drug formulary where it is, we could come up with price controls, but we all want to see the next miracle medicine, the cure for Alzheimer's, the cure for AIDS, the cure for Parkinson's. It is the prescription drug industry that is most likely to bring us that next generation of miracles.

Finally, I think we may want to look also at advertising and what the laws are with respect to prescription medicine advertising. I think there are a lot of things that are on the table that could achieve or help to achieve our goal, which is to lower the cost of miracle medicines to the consumer and make sure people continue to have health coverage through their employer.

I look forward to hearing the testimony today. I look forward to learning more about this issue in my district and my constituents, but I agree with many of the things that have been said previously. But the first step is to deal with those who are most in need, and that is our seniors. We need to add a prescription drug benefit to Medicare.

Thank you, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentlelady. Mr. Shadegg, for an opening statement.

Mr. SHADEGG. Thank you, Mr. Chairman, and I, too, want to express my appreciation for your holding this important hearing today. There are many laws that come before this Congress which are not truly within the ambit of our responsibility, but the Constitution specifically gives the U.S. Congress the power to enact laws relating to patents. So this is our responsibility, and in this instance I think it is an extremely important responsibility.

Just as Thomas Jefferson and James Madison differed over the merits of patent laws over 200 years ago, today there is an honest and genuine debate over the regulatory environment surrounding our pharmaceutical patents and our pharmaceutical industry. That debate deserves this hearing and deserves careful consideration.

This is an incredibly complicated subject. My constituents do not understand the 30-month stay or the 180-day market exclusivity, but, Mr. Chairman, they clearly do understand and are concerned about the double-digit increase in the cost of prescription drugs and the double-digit increase in health insurance premiums. We simply as a nation cannot tolerate cost increasing at those rates.

Now my constituents, Mr. Chairman, deeply value innovative medicines and are very much appreciative of the miracle drugs which have been produced. They also understand that producing those drugs is a capital-intensive process, and that if that capital isn't there, those drugs won't come to market.

But, Mr. Chairman, it is important that we strike an appropriate balance. Some say, for example, that Hatch-Waxman strikes that proper balance. Others, of course, strongly disagree and say there are loopholes. I believe, indeed, that there have been some abuses, perhaps abuses on both sides, and we must fix this system.

It seems to me that the witnesses today can bring us important evidence on that issue and that we owe it to our constituents to examine these laws and to ensure that they are correctly crafted. The miracle drugs that make our health care system the best in the world need to come to market. At the same time, the laws that allow those drugs to come to market should not be abused or twisted or used in a way to protect the market for one company long beyond what was intended and to keep others out of the market.

This seems to me to be one of the most important challenges facing this Congress. We must strike the right balance. I am of the mind that we have not struck that balance correctly, that there are loopholes which need to be repaired and which need to be examined by this Congress. I am anxious to hear the evidence here today. I think this is an important, critically important, obligation for us because of the importance of health care to all Americans.

I thank you, Mr. Chairman, for holding the hearing.

Mr. BILIRAKIS. And I thank the gentleman, and would yield to Mr. Buyer for an opening statement, 3 minutes, please.

Mr. BUYER. For all my education, I will articulate the word "pass."

I want to let us hear the witnesses.

Mr. BILIRAKIS. Mr. Deal, for an opening statement.

Mr. DEAL. Pass.

Mr. BILIRAKIS. "Pass"—I like those opening statements.

All right, that completes all of our opening statements, I do believe.

[Additional statement submitted for the record follows:]

PREPARED STATEMENT OF HON. ALBERT R. WYNN, A REPRESENTATIVE IN CONGRESS
FROM THE STATE OF MARYLAND

Mr. Chairman, thank you for holding this important hearing on whether there is adequate competition amongst brand and generic drugs, and whether improvements allowing for greater competition in the drug marketplace are necessary.

Clearly, with the rising costs of prescription drugs and an inadequate prescription drug benefit, we should look at ways to lower prescription drug costs without providing a significant disincentive for brand drug companies from innovating.

The issue of drug patents and the entry of generic drugs on the marketplace is interesting and complex subject. In 1984, the Hatch-Waxman legislation streamlined the generic drug approval process, and restored the patent life lost during the FDA approval process for the innovator of the drug.

Since 1984, generics have risen from less than 20 percent to roughly 50 percent of all prescription drugs dispensed. At the same time, brand investment in research and development has increased to nearly \$30 billion.

However, there are some concerns that some name brand manufacturers are preventing generic competition. Unfortunately, a lack of competition in the drug industry translates into higher prices for consumers.

On the Senate side, S. 812 passed in July, which would allow generic drugs to get on the market more easily. I would like to hear from our witnesses about the impact that the measure would have in the industry—brand and generics—as well as consumers should it pass.

I am hopeful that today's hearing will shed some light on the Hatch-Waxman bill and possible modifications that need to make in this day and age.

Mr. BILIRAKIS. What I would like to announce at this point is that we will hear the statements of the witnesses of the first panel, Dr. Crawford and Mr. Muris. Then we will break for 45 minutes to give everybody a chance to grab a quick bite or whatever the case may be. I hope it doesn't inconvenience you two gentlemen too very much, but give the opportunity, because I know there are people here who want to hear your testimony. I don't want to break, take that away from them. Is that all right, Dr. Crawford?

Mr. CRAWFORD. Yes.

Mr. BILIRAKIS. All right. When we return after that 45 minutes, then we will go into the questioning of the first panel.

Mr. BROWN. Mr. Chairman, I would like to ask unanimous consent to submit several documents for the record, distribute this "Pray for a miracle" PhRMA ad I mentioned in my remarks, and other testimony from Business for Affordable Medicine, if I could.

Mr. BILIRAKIS. Without objection, those will be made a part of the record.

[The prepared statement of Business for Affordable Medicine follows:]

PREPARED STATEMENT OF BUSINESS FOR AFFORDABLE MEDICINE

Mr. Chairman, on behalf of Business for Affordable Medicine, we appreciate the opportunity to present our views on the need for reform of the 1984 Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act).

BAM is a non-partisan coalition of Governors, large employers, and labor leaders committed to containing drug costs by improving pharmaceutical competition. Our complete focus has been on helping Congress understand the need to reform the Hatch-Waxman Act.

CONSUMERS AND OTHER PURCHASERS NEED HELP

No problem poses a greater threat to the economic well being of American consumers than the rising cost of prescription drugs. Our aging population is faced with the promise of longer and healthier lives as a result of important pharmaceutical discoveries, but we also face a nearly unbearable burden of paying for these medicines at rates that are breaking the budgets of consumers, states, and other purchasers.

Americans will spend an estimated \$4.7 trillion for prescription drugs over the next 10 years. Today, the cost of drugs is rising at nearly 20 percent annually. Those who can afford to pay are finding their budgets and patience wearing thin. Seniors, employers, government agencies, and taxpayers who must foot the largest part of the bill—including millions of Americans without insurance—are desperate for help.

CONGRESS MUST CLOSE HATCH-WAXMAN ACT LOOPHOLES

Pending legislation before this committee provides Congress with the greatest opportunity in nearly two decades to make a difference. By closing loopholes in the Hatch-Waxman Act, HR 5311 will stop tactics by drug companies that prevent access to lower-cost generics. This simple effort will save Americans \$60 billion in prescription drug costs over the next 10 years, according to the Congressional Budget Office.

The Hatch-Waxman Act was passed in 1984 to encourage drug manufacturers to invest in research and development of new drugs. The law was also intended to ensure that lower-cost generic drugs would be available immediately after specifically designated market exclusivities provided under the Act expired. The problem is, drug manufacturers block access to more affordable generics even after these exclusivity periods expire.

CASE STUDY—PRILOSEC

Among many examples of abuse, we encourage the committee to closely examine the actions by the manufacturer of Prilosec. British-based AstraZeneca manufactures Prilosec (omeprazole), the most prescribed drug in America for seniors. The base patents and market exclusivities that were intended to protect Prilosec from generic competition expired three years ago. Despite this fact, AstraZeneca has engaged in an apparently carefully crafted strategy to use provisions of the Hatch-Waxman Act together with other legal maneuvers to prevent generic sales.

First, AstraZeneca listed a patent with the FDA that covered the metabolite created in patients who ingest Prilosec. It also listed patents that cover the use of the drug with antibiotics, and that covered formulations not used to make or market the product.

None of these patents covered approved “methods or uses” of the product. The result was to create a situation where generic manufacturers must litigate 90 claims on six patents, making it impossible to resolve any dispute within the 30-month stay provided under the Act. The fact that every patent adjudicated so far has been struck down by the courts seems to indicate that AstraZeneca took unfair advantage of the Hatch-Waxman provisions relating to listing of patents.

Second, while patent term extensions were provided in the Hatch-Waxman Act in return for explicitly established obligations on patent holders to reasonably cooperate with litigants to expedite claims, AstraZeneca has taken advantage of the provisions without upholding its obligations under the Act.

AstraZeneca sued generic manufacturers in May 1998, but waited until late-1999 to respond to discovery requests, waited more than a year after filing the suit to file for multi-district consideration of the cases, and then argued that the cases should be returned to their original jurisdictions. AstraZeneca also obtained another patent in January 2000, and then waited nine months—after discovery ended in its litigation against generic competitors—to include the patent in the trial. Subsequent actions to delay the case resulted in an order by the court that condemned AstraZeneca’s “utter failure” to comply with discovery obligations.

Third, AstraZeneca listed four additional patents in March 2001 to obtain a 45-day extension of its market exclusivity. This tactic prevented FDA action to approve generic competitors until AstraZeneca could complete separate filings on unrelated patents and obtain a six-month extension under the pediatric testing law.

These actions make it impossible for purchasers to believe that the courts can adequately address abuses of the Hatch-Waxman Act, as some on the committee suggest.

THE SYSTEM FOR REGULATING PHARMACEUTICAL COMPETITION IS BREAKING DOWN

In fact, we are witnessing an outbreak of litigation by the Federal Trade Commission, state Attorneys General, and class action attorneys to claim damages from drug manufacturers for their actions. Rather than address legitimate claims that were contemplated by the Act, the courts are becoming filled with claims outside the Act because of its failures.

It is particularly alarming to purchasers that the Act provides no regulatory avenue for relief to those harmed by apparently unlawful actions not anticipated by its framers—such as listing of patents with the FDA that do not cover approved methods or uses of a drug, filing of questionable citizen petitions that intentionally delay generic drug approvals, and frivolous litigation intended to trigger Hatch-Waxman provisions that also delay generic approvals.

It is further alarming that the Act also does not allow any purchaser to have standing in court to contest alleged abuses of the Act. The result is a proliferation

of litigation under anti-trust and anti-consumer laws that we believe could overwhelm the judicial system, lead to further breakdown in the pharmaceutical market, and ultimately harm the ability of the drug industry to remain competitive and robust.

We also encourage the committee to consider the extent to which drug companies are misleading government agencies to obtain patents and trigger 30-month stays on FDA approvals of generic products. The tactic seems to be gaining popularity within the industry, and has been cited by the courts in cases relating to Buspar (an anxiety drug manufactured by Bristol Myers-Squibb), Tiazac (a heart drug manufactured by Biovail), and Prilosec.

INACTION BY CONGRESS IS COSTING BILLIONS OF DOLLARS

Failure of the Hatch-Waxman Act to protect the interests of purchasers—including state and federal taxpayers, consumers, and employers is a growing problem at a time when billions of dollars worth of patented drugs face competition over the next few years.

For example, Medicaid agencies in 46 states spent \$1.2 billion dollars last year to purchase 16 prescription drugs that face patent expiration over the next three years. The nation's largest employers spent over \$2 billion to purchase the same drugs, including Augmentin, Relafin, Flonase, Cipro, and Wellbutrin. Purchasers should expect to save 50 percent or more when the patents and exclusivities on these drugs expire and generic alternatives become available.

Unfortunately, we have little faith that consumers will see these savings any time soon because loopholes in the Hatch-Waxman Act enable drug manufacturers to delay generic competition for months and, in some cases, years.

Though generic competition for Prilosec should have begun in October 2001, seniors, consumers, employers and taxpayers have paid nearly \$3 billion more over the past year—or nearly \$6 million each day—than necessary for Prilosec.

The brand drug industry will claim that generic manufacturers could make their products available to compete against Prilosec at any time. We predict, however, that they will refuse to discuss with this committee the brand industry strategy built around shortcomings of the Hatch-Waxman Act that has made launches of generic Prilosec all but impossible.

PURCHASERS HAVE DONE EVERYTHING POSSIBLE

Purchasers are doing everything possible on their own to reign in the growing cost of prescription drugs. For example, West Virginia produces significant savings by waiving co-payments for some generic drugs used by state employees. In South Dakota, the state Medicaid program requires physicians to obtain authorization before prescribing specific high cost drugs for which more affordable alternatives may be as good. Vermont and other states use preferred drug lists, which ensure their programs obtain the best possible rates from manufacturers who must compete on price.

Employers are also finding ways to cut costs by negotiating directly with drug manufacturers, increasing generic utilization, and changing formularies. Their only remaining option is to reduce or eliminate prescription drug coverage altogether, a move that is picking up steam in corporate boardrooms.

None of these efforts changes the fact that the nation will still waste billions of dollars to purchase drugs that should face generic competition. In fact, pharmaceutical purchasers are now counting entirely on Congress to fix the problem.

The U.S. Senate responded on July 31, 2002 in a way that gives purchasers real hope. Bipartisan legislation passed by a vote of 78-21 to provide genuine prescription drug cost relief by closing the most abusive loopholes in the Hatch-Waxman Act.

RESPONSE TO DRUG INDUSTRY OPPOSITION

While drug lobbyists argue that Congress should limit its focus to passing a Medicare prescription drug bill, it is plain to the rest of us that spending more taxpayer funds for prescription drugs without also ensuring faster access to generics makes no sense.

The drug industry also points out that only six percent of generic drug applications since passage of the Hatch-Waxman Act have faced approval delays. In fact, while few generics faced approval delays in the early years, the majority face delays today. It is also a fact that manufacturers now delay competition for virtually all blockbuster drugs.

Washington needs to face this reality. The Federal Trade Commission report issued in July 2002 clearly highlights the drug industry's growing efforts to "game

the system” and delay the introduction of generic competition through the Hatch-Waxman Act. Even drug industry leaders acknowledge the problem. Novartis chairman and CEO Daniel Vasella told the media on June 6, 2002 that industry practices to delay competition are not fair. “One has to accept that drug patents do indeed have an end,” he told USA Today.

The committee should consider these facts apart from the rhetoric provided by the drug industry. A recent national survey by AARP found that 81 percent of Americans over the age of 45 believe Congress should pass legislation this year to make generic drugs more available. Support for this legislation is strong among Republicans (83 percent), Democrats (86 percent) or Independents (84 percent).

Finally, we hope the House will not buy into the drug industry’s claim that passing Hatch-Waxman reform legislation will result in cut backs on research and development for new drugs. In fact, increased spending by the drug industry on research since 1984 is a result of generic competition, not in spite of it. Reduced competition resulting from an aging Act and ensured by legislative non-action will surely lead to less, not more investment in research.

The AARP survey found that an overwhelming majority of Americans (73 percent) do not buy the drug industry scare tactic. In fact, 77 percent of survey participants identifying themselves as either Republican or Democrat see threats of diminished research investment in the face of increased competition as nothing more than a smoke screen.

We encourage the committee to immediately pass HR 5311 so the House of Representatives can pass Hatch-Waxman reform legislation before Congress adjourns this month. Billions of dollars are at stake. To do nothing this year will be a costly disappointment to every consumer in America. We urge you to provide genuine cost relief to all prescription drug purchasers by ending the delay tactics Americans can no longer afford.

Thank you for the opportunity to make our views known.

Mr. BILIRAKIS. The Chair now yields to Dr. Crawford. I would advise you both that your written statement is a part of the record, and, hopefully, you would sort of complement it, if you will, supplement it. Thank you, Doctor. Please proceed.

STATEMENTS OF HON. LESTER M. CRAWFORD, ACTING COMMISSIONER, FOOD AND DRUG ADMINISTRATION; ACCOMPANIED BY DANIEL E. TROY, CHIEF COUNSEL, FOOD AND DRUG ADMINISTRATION; AND HON. TIMOTHY J. MURIS, CHAIRMAN, FEDERAL TRADE COMMISSION

Mr. CRAWFORD. I am joined at the table by Daniel E. Troy, who is Chief Counsel of FDA.

Before I go further, I would like to congratulate the House for the passage of the Medical Device User Fee Act. This is very important to the Food and Drug Administration, and I am very pleased to hear that that is one of the items that you addressed recently.

I am going to discuss FDA’s implementation of the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman amendments. I will also discuss the Federal Trade Commission’s report on patent issues as they affect the approval of generic drugs.

Since its enactment in 1984, Hatch-Waxman has become a valuable tool in making medications more affordable for American citizens. To date, FDA has approved more than 10,000 generic drug products, providing high-quality, lower-cost prescription drugs to millions of consumers.

Two of the key Hatch-Waxman provisions, however, have recently become associated with possible anti-competitive behavior, provisions for 180 days of marketing exclusivity for certain generic drug sponsors and for a 30-month stay on generic drug approvals while patent infringement issues are litigated.

Section 505(j) of the Food, Drug and Cosmetic Act governs the Abbreviated New Drug Application, or ANDA, approval process. This permits generic versions of existing innovator drugs to be approved without submission of a full New Drug Application, or NDA.

NDAs must include information about patents claiming a drug product, which FDA then lists in a publication called the “Orange Book.” ANDAs must include a certification for each patent listed in the Orange Book for the innovator drug. A so-called paragraph (IV) certification begins the process in which the validity of the listed patent or infringement by the generic product may be determined by the courts.

If the NDA sponsor or patent owner files a patent infringement suit against the ANDA sponsor, FDA cannot approve the ANDA for at least 30 months from the date of the notice unless the court reaches an earlier decision. In return for risking a patent infringement lawsuit, the statute provides an incentive of 180 days of marketing exclusivity to the first generic applicant who challenges a listed patent.

The 180-day exclusivity provision has been the subject of a series of Federal court decisions in recent years. Most notably, the courts have determined that the meaning of a court decision that begins 180-day exclusivity may be the decision of a district court if it finds the patent to be invalid, unenforceable, or not infringed.

FDA had previously interpreted a court decision as a final decision of an appellate court, generally the Federal circuit. We took this position so that generic manufacturers would not run the risk of being subject to treble damages for marketing a drug if the appeals court ruled against it.

Concerns have been expressed over FDA’s role in the listing of patents in the Orange Book, which can delay generic drug approvals and the initiation of the 180-day exclusivity. As noted before, an applicant seeking approval for an ANDA must submit a certification to relevant listed patents. Under current law, even an applicant whose ANDA is pending must certify to any new patent submitted for listing by the sponsor within 30 days after they are issued by the Patent and Trademark Office.

Clearly, when an innovator company submits a new patent listing to FDA for an existing product, the process of patent certification, the 45-day waiting period, litigation, and a 30-month stay can result in a considerable delay in the approval of a generic product. Indeed, a pending generic drug application may be subject to multiple, overlapping stays if new patents are listed for the innovator drug.

Of the 442 active ANDAs containing paragraph (IV) certifications, only 17 have had multiple 30-month stays. However, a significant number of these products have high-dollar-value annual sales, and in some instances multiple stays have resulted in the delay of generic drug approval for years.

FDA does not undertake an independent review of the patent submitted by the NDA sponsor. The statute requires FDA to publish patent information upon approval of the NDA, thus, making the agency’s role ministerial.

Generic and innovator firms may resolve any disputes concerning patent listings in private litigation. Some have suggested that FDA

should review drug patents to determine if they should be listed in the Orange Book. We believe that FDA should not review drug patents because we do not have the expertise to make these assessments. It would fail to speed the availability of generic drugs.

I want to commend the FTC for their comprehensive study on these issues. FDA has found the factual information provided in the report to be extremely valuable in our own discussions on the generic drug approval process.

FTC recommends that only one 30-month stay be allowed for infringement disputes over patents listed in the Orange Book prior to the filing date of the NDA. FDA is sympathetic to this recommendation. FDA agrees that recently more ANDAs have been subject to 30-month stays than in years past, and that more patents on average are now being litigated for generic drug application than formerly.

We would also like to note that the FTC report recognized that FDA does not have the capacity to review the appropriateness of patent listings. While FDA and the administration share a deep concern about the cost of drugs, we are opposed to S. 812, the Greater Access to Affordable Pharmaceuticals Act, because it would harm innovation and investment in new medicines, encourage litigation around new drug approval and the filing of patents, reduce patent protections for drug developers, and delay the availability of generic drugs.

Rather than this harmful approach, the administration strongly supports the bill passed by the House earlier this year to provide a prescription drug benefit under Medicare. Under S. 812, sponsors who fail to file patent information for the Orange Book by certain deadlines permanently lose the right to bring future lawsuits for patent infringement. Similarly, if an innovator fails to file a lawsuit and obtain a preliminary injunction within 45 days of a paragraph (IV) challenge, it would be permanently barred from taking future actions to protect the patent. These are unacceptable rollbacks in the rights of patent-holders that will stifle innovation.

In addition, provisions for rolling exclusivity would actually reduce access to affordable drugs, as consumers would have to wait longer for the entry of the second, third, and succeeding generic versions of a product, which is when significant price reduction takes place.

In conclusion, Mr. Chairman, FDA has been actively engaged in addressing the issues that have been raised by brand-name and generics companies concerning the operation of the statute. We continue to implement the Hatch-Waxman amendments as best we can, given the statutory checks. In doing so, we have tried to maintain a balance between protecting innovation in drug development and expediting the approval of lower-cost drugs.

Thank you very much.

[The prepared statement of Hon. Lester M. Crawford follows:]

PREPARED STATEMENT OF LESTER M. CRAWFORD, DEPUTY COMMISSIONER OF FOOD AND DRUGS, FOOD AND DRUG ADMINISTRATION

Mr. Chairman and Members of the Subcommittee, I am Dr. Lester M. Crawford, Deputy Commissioner of Food and Drugs. I am pleased to be with you today to discuss the Food and Drug Administration's (FDA) implementation of the Drug Price

Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Amendments.

This testimony will discuss a number of issues which affect the timely introduction of generic drugs into the U.S. marketplace. It will focus in particular, as you requested, on the question of whether certain “later-listed” patent filings by the sponsors or manufacturers of innovator drug products have resulted in the delay of generic drug approvals by the Food and Drug Administration (FDA or the Agency).

The Hatch-Waxman Amendments were intended to balance two important public policy goals. First, Congress wanted to ensure that brand-name drug manufacturers have meaningful market protection to encourage the development of valuable new drugs. Second, once the statutory patent protection and marketing exclusivity for these new drugs has expired, consumers benefit from the rapid availability of lower priced generic versions of innovator drugs.

Since its enactment in 1984, Hatch-Waxman has governed the generic drug approval process. One of its key provisions provides 180 days of marketing exclusivity to certain generic drug applicants. The 180-day generic drug exclusivity provision is one component of the complex patent listing and certification process, which also provides for a 30-month stay on generic drug approvals while certain patent infringement issues are litigated. Both of these provisions are discussed in detail below.

STATUTORY PROVISIONS

The Hatch-Waxman Amendments amended the Federal Food, Drug, and Cosmetic (FD&C) Act and created section 505(j). Section 505(j) established the abbreviated new drug application (ANDA) approval process, which permits generic versions of previously approved innovator drugs to be approved without submission of a full new drug application (NDA). An ANDA refers to a previously approved NDA (the “listed drug”) and relies upon the Agency’s finding of safety and effectiveness for that drug product.

The timing of an ANDA approval depends in part on patent protections for the innovator drug. Innovator drug applicants must include, in an NDA, information about patents for the drug product that is the subject of the NDA. FDA publishes patent information on approved drug products in the Agency’s publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as the “Orange Book.” The book is printed yearly by the Government Printing Office and is updated monthly and available to the public. It lists all approved drug products with their therapeutic equivalence codes in addition to the products’ patent and exclusivity information (if such information exists). The “Orange Book” is also publicly available on FDA’s website.

The FD&C Act requires that generic drug applicants include, in their ANDAs, a certification for each patent listed in the “Orange Book” for the innovator drug. This certification must state one of the following:

- (I) that the required patent information relating to such patent has not been filed;
- (II) that such patent has expired;
- (III) that the patent will expire on a particular date; or
- (IV) that such patent is invalid or will not be infringed by the drug, for which approval is being sought.

A certification under paragraph I or II permits the ANDA to be approved immediately, if it is otherwise eligible. A certification under paragraph III indicates that the ANDA may be approved on the patent expiration date.

A paragraph IV certification, however, begins a process in which the question of whether the listed patent is valid or will be infringed by the proposed generic product may be answered by the courts prior to the expiration of the patent. The ANDA applicant who files a paragraph IV certification to a listed patent must notify the patent owner and the NDA holder for the listed drug that it has filed an ANDA containing a patent challenge. The notice must include a detailed statement of the factual and legal basis for the ANDA applicant’s opinion that the patent is not valid or will not be infringed. The submission of an ANDA for a drug product claimed in a patent is an infringing act if the generic product is intended to be marketed before expiration of the patent, and therefore, the ANDA applicant who submits an application containing a paragraph IV certification may be sued for patent infringement. If the NDA sponsor or patent owner files a patent infringement suit against the ANDA applicant within 45 days of the receipt of notice, FDA may not give final approval to the ANDA for at least 30 months from the date of the notice. This 30-month stay will apply unless the court reaches a decision earlier in the patent infringement case or otherwise orders a longer or shorter period for the stay. A court

may modify the length of a stay, under the FD&C Act, “if either party in the action failed to reasonably cooperate in expediting the action.” (21 U.S.C. 335(j)(5)(iii)).

The statute provides an incentive of 180 days of market exclusivity to the “first” generic applicant who challenges a listed patent by filing a paragraph IV certification and thereby runs the risk of having to defend a patent infringement suit. The statute provides that the first applicant to file a substantially complete ANDA containing a paragraph IV certification to a listed patent will be eligible for a 180-day period of exclusivity beginning either from the date it begins commercial marketing of the generic drug product, or from the date of a court decision finding the patent invalid, unenforceable or not infringed, whichever is first. These two events—first commercial marketing and a court decision favorable to the generic—are often called “triggering” events, because under the statute they can trigger the beginning of the 180-day exclusivity period.

In some circumstances, an applicant who obtains 180-day exclusivity may be the sole marketer of a generic competitor to the innovator product for 180 days. But 180-day exclusivity can begin to run—with a court decision—even before an applicant has received approval for its ANDA. In that case, some, or all of the 180-day period, could expire without the ANDA applicant marketing its generic drug. Conversely, if there is no court decision and the first applicant does not begin commercial marketing of the generic drug, there may be prolonged or indefinite delays in the beginning of the first applicant’s 180-day exclusivity period. Approval of an ANDA has no effect on exclusivity, except if the sponsor begins to market the approved generic drug. Until an eligible ANDA applicant’s 180-day exclusivity period has expired, FDA cannot approve subsequently submitted ANDAs for the same drug, even if the later ANDAs are otherwise ready for approval and the sponsors are willing to immediately begin marketing. Therefore, an ANDA applicant who is eligible for exclusivity is often in the position to delay all generic competition for the innovator product.

Only an ANDA containing a paragraph IV certification may be eligible for exclusivity. If an applicant changes from a paragraph IV certification to a paragraph III certification, for example upon losing its patent infringement litigation, the ANDA will no longer be eligible for exclusivity.

COURT DECISIONS AND FDA ACTIONS

The 180-day exclusivity provision has been the subject of considerable litigation and administrative review in recent years, as the courts, industry, and FDA have sought to interpret it in a way that is consistent both with the statutory text and with the legislative goals underlying the Hatch-Waxman Amendments. A series of Federal court decisions beginning with the 1998 *Mova*¹ case describe acceptable interpretations of the 180-day exclusivity provision, identify potential problems in implementing the statute, and establish certain principles to be used by the Agency in interpreting the statute. As described in a June 1998 guidance for industry, FDA currently is addressing on a case-by-case basis those 180-day exclusivity issues not addressed by existing regulations.

One of the most fundamental changes to the 180-day exclusivity program, resulting from the legal challenges to FDA’s regulations, is the determination by the courts of the meaning of the phrase “court decision.” The courts have determined that the “court decision” that can begin the running of the 180-day exclusivity period may be the decision of the district court, if it finds that the patent at issue is invalid, unenforceable, or will not be infringed by the generic drug product. FDA had interpreted the “court decision” that could begin the running of 180-day exclusivity (and the approval of the ANDA) as the final decision of a court from which no appeal can be or has been taken—generally a decision of the Federal Circuit. FDA’s interpretation had meant that an ANDA applicant could wait until the appeals court had finally resolved the patent infringement or validity question before beginning the marketing of the generic drug.

FDA had taken this position so that the generic manufacturer would not have to run the risk of being subject to potential treble damages for marketing the drug, if the appeals court ruled in favor of the patent holder. The current interpretation means that if the 180-day exclusivity is triggered by a decision favorable to the ANDA applicant in the district court, the ANDA sponsor who begins to market during that exclusivity period now may run the risk of treble damages if the district court decision is reversed on appeal to the Federal Circuit. As a practical matter, it means that many generic applicants may choose not to market the generic and thus the 180-day exclusivity period could run during the pendency of an appeal.

¹ *Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060, 1065 (D.C. Cir. 1998).

“ORANGE BOOK” LISTINGS

Concerns have been expressed over FDA’s role in the listing of patents in the “Orange Book,” which can have an impact on generic drug approvals by delaying their approval and the initiation of 180-day exclusivity. Under the FD&C Act, pharmaceutical companies seeking to market innovator drugs must submit, as part of an NDA or supplement, information on any patent that 1) claims the pending or approved drug or a method of using the approved drug, and 2) for which a claim of patent infringement could reasonably be asserted against an unauthorized party. Patents that may be submitted are drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method of use patents. Process (or manufacturing) patents may not be submitted to FDA.

When an NDA applicant submits a patent covering the formulation, composition, or method of using an approved drug, the applicant must also submit a signed declaration stating that the patent covers the formulation, composition, or use of the approved product. The required text of the declaration is described in FDA’s regulations.

The process of patent certification, notice to the NDA holder and patent owner, a 45-day waiting period, possible patent infringement litigation and the statutory 30-month stay may result in a considerable delay in the approval of ANDAs when an innovator company submits a new patent listing to FDA. Therefore, ANDA applicants often closely scrutinize these listings. FDA regulations provide that, in the event of a dispute as to the accuracy or relevance of patent information submitted to and subsequently listed by FDA, an ANDA applicant must provide written notification of the grounds for dispute to the Agency. FDA then requests the NDA holder to confirm the correctness of the patent information and listing. Unless the patent information is withdrawn or amended by the NDA holder, FDA will not change the patent information in the “Orange Book.”

If a patent is listed in the “Orange Book,” an applicant seeking approval for an ANDA must submit a certification to the patent. Even an applicant whose ANDA is pending when additional patents are submitted for listing by the sponsor must certify to the new patents, unless the additional patents are submitted by the patent holder more than 30-days after issuance by the U.S. Patent and Trademark Office. Moreover, a pending generic drug application may be subject to multiple overlapping 30-month stays if new patents are listed for the innovator drug. A review of FDA’s records indicates that of the 442 active ANDAs that contain paragraph IV certifications, only 17 have had multiple 30-month stays, representing 3.8 percent of all applications with patent challenges. However, we note that a significant number of these products have high dollar value annual sales, and we are aware of some instances where multiple stays have resulted in the delay of a generic drug approval for a number of years.

FDA does not undertake an independent review of the patents submitted by the NDA sponsor. Issues of patent claim and infringement are matters of patent law, and FDA does not have the authority as well as the resources or capability to assess whether a submitted patent claims an approved drug and whether a claim of patent infringement could reasonably be made against an unauthorized use of the patented drug. FDA has implemented the statutory patent listing provisions by informing interested parties of what patent information is to be submitted, who must submit the information, and when and where to submit the information. The statute requires FDA to publish patent information upon approval of the NDA and, therefore, the Agency’s role in the patent-listing process is ministerial. The Agency relies on the NDA holder or patent owner’s signed declaration stating that the patent covers an approved drug product’s formulation, composition or use. Generic and innovator firms may resolve any disputes concerning patents in private litigation.²

The Agency is aware that in the past couple of years there have been new patents submitted to FDA for listing in the “Orange Book” shortly before patents already listed in the “Orange Book” are scheduled to expire. These new patents have been submitted to FDA within the required 30-days of issuance by the Patent and Trademark Office. If the NDA sponsor complies with the requirements of the statute and regulations in submitting a patent for listing in the “Orange Book,” the Agency has no discretion to reject a patent merely on the basis that, but for the filing of the patent, ANDAs would be eligible for final approval.

It has been suggested that FDA should review drug patents to determine if they should be listed in the “Orange Book” as protection for innovator drug products—that is, FDA should assess whether a submitted patent properly claims the ap-

²*Mylan v. Thompson*, 268 F.3d 1323 (Fed Cir. 2001)—A generic’s claim of improper listing “Is not a recognized defense to patent infringement.”

proved drug product and could support a claim of patent infringement. The Agency believes that it should not review drug patents because such a review would be time consuming and would not speed the availability of generic drugs, but instead add a layer of complexity and delay.

Because it is not established that FDA has authority under the FD&C Act to make substantive patent assessments, there would be lengthy litigation before the scope of Agency authority is established. FDA review of patents is unlikely to speed approval and marketing of generic drugs in a meaningful way because even if FDA were to decide not to list a patent, the innovator company could obtain an injunction against approval or marketing of the generic drug until the patent listing question is resolved. In such a case, FDA's review of the patents would have done nothing to speed approval of generic drugs. Patent reviews would lead to substantial litigation that will impose a new and substantial burden on FDA's Office of the Chief Counsel and Department of Justice litigation resources. Finally, the Agency does not have the resources or expertise to review patents and, even with additional funding, is unlikely to be able to obtain adequate expert resources to do so.

FEDERAL TRADE COMMISSION STUDY

In response to reports of brand-name and generic drug companies engaging in anti-competitive behavior, the Federal Trade Commission (FTC) conducted a study to determine if the 180-day exclusivity and the 30-month stay provisions of the Hatch-Waxman Amendments are used strategically to delay consumer access to generic drugs. In July 2002, FTC published the findings of their study and provided two primary recommendations.

FTC recommends that only one automatic 30-month stay per drug product per ANDA be permitted to resolve infringement disputes over patents listed in the "Orange Book" prior to the filing date of the generic applicant's ANDA. FDA is sympathetic to the recommendation for a single 30-month stay. FDA also agrees with FTC that recently, more ANDAs have been subject to 30-month stays than in years past, and that more patents on average are now being litigated per generic drug application than in the past.

FTC's second recommendation is to pass legislation to require brand-name companies and first generic applicants to provide copies of certain agreements to FTC. This is a response to FTC's finding that brand-name companies and first generic applicants have on occasion entered into agreements to delay generic competition. FDA has no objection to this recommendation.

FDA agrees with many of the conclusions of the FTC study and has found the factual information provided in the report to be extremely valuable in our own deliberations regarding the generic drug approval process. One example of this is the compilation of information on the disposition of litigation surrounding patents filed after NDA approval. Currently, the Agency is considering a citizen petition submitted by FTC concerning the appropriateness of listing patents that cover polymorphs, which are forms of the active ingredients of approved drugs different from the actual form approved in the NDA.

Finally, we note that FTC's report recognized that FDA does not have the capacity to review the appropriateness of patent listings.

OTHER SIGNIFICANT BARRIERS TO GENERIC DRUG AVAILABILITY

Although patent-related challenges have delayed approval of generic drugs in a number of high-profile cases, there are a number of other important barriers to generic competition. These barriers, which usually result from insufficient scientific knowledge and standards, are likely to become even more significant as scientific advances in drug development lead to new forms of therapy.

Currently, some classes of drug products entirely lack generic versions because scientific methods for evaluating their bioequivalence are not available. Examples include the nasal and inhaled corticosteroids used for allergy and asthma treatment. Prospective manufacturers of inhaled or topical generic drugs face uncertainty and high development costs, and thus few such products have been developed. Other widely used drugs, such as conjugated estrogens (available since the 1940's), lack generic competition due to scientific uncertainty about the composition of the active ingredient (s). Disputes over composition and bioequivalence standards also have caused delays in approval of many generic drugs while innovator challenges to the standards are evaluated. Scientific research to support the development of additional standards in these areas would enable FDA to approve drugs in additional classes, and also to deal with scientific challenges to pending generic drug approvals more expeditiously.

Innovations in drug therapy are leading to new methods of drug delivery, including via liposomes, implantable systems, transcutaneous or transmucosal products, and inhalation methods. At the same time, due to innovations in chemistry, drugs with very complex molecular structures are possible.

If generic copies of such innovative therapies are eventually to be made available, standards must be developed to accommodate these products within the Hatch-Waxman framework. This includes work on issues of composition, formulation and bio-equivalence. Scientific research in each of these areas is needed to support new standards.

LEGISLATION

On July 31, the Senate passed S. 812, the Greater Access to Affordable Pharmaceuticals Act, sponsored by Senators Schumer (D-NY) and McCain (R-AZ). The Administration is opposed to this bill on the grounds that it would 1) harm innovation and investment in new medicines; 2) encourage litigation around the initial approval of new drugs and the filing of patents; 3) reduce patent protections for drug developers; and 4) delay availability of generic drugs and reduce price competition. The Senate also attached provisions to allow the importation of drugs from Canada that we believe would jeopardize the health and safety of the nation's consumers. The Administration supports the approach to drug price relief taken by the House of Representatives earlier this year, in passing legislation to provide a prescription drug benefit under Medicare.

Provisions of S. 812 require sponsors to file patent information for "Orange Book" listings no later than 30 days after NDA approval, or 30 days after patents are issued for drugs already having NDA approval. Failure to file within these timeframes will permanently bar patent holders from bringing suits for patent infringement. The Administration believes this would be an unacceptable rollback in the rights of patent holders. Provisions to allow generic manufacturers to sue sponsors to correct or delete patent listings would encourage lawsuits.

The Administration also opposes provisions that would allow innovators to protect their patents filed more than 30 days after NDA approval only by filing an infringement lawsuit and obtaining a preliminary injunction within 45-days of receiving notification of a paragraph IV challenge. If no lawsuit has been filed after 45 days have elapsed, the innovator would be permanently barred from filing future infringement suits to protect the patent.

In addition, provisions for "rolling" 180-day exclusivity will actually reduce access to affordable pharmaceuticals, as consumers would have to wait longer for the second or third generic approvals after the expiration of exclusivity, which is when significant price reduction occurs. These provisions would also generate extensive litigation over the timing and validity of triggering events.

Finally, we note that provisions to allow the importation of drugs from Canada by individuals, pharmacists and wholesalers, would open up the current "closed" drug distribution system to drugs of unknown quality, authenticity and origin. These provisions create opportunities for counterfeiting, drug diversion, and fraud.

CONCLUSION

FDA has been actively engaged in addressing the issues that have been raised by brand name and generics companies concerning the operation of the statute. We held a symposium in January 2002 where the generic and innovator industries engaged FDA in a discussion and debate on the issues each side wanted to bring to the Agency's attention. Issues included the 30-month stay, 180-day exclusivity, and patent listing, as well as other questions such as the use of citizen petitions and their role in approval of generic drugs.

FDA continues to implement the Hatch-Waxman Amendments exclusivity provisions in the best manner possible given the text of the legislation, the history of the legislation and the numerous court challenges. In doing so, FDA has tried to maintain a balance between innovation in drug development and expediting the approval of lower-cost generic drugs, as Congress sought to do in enacting this statute.

Thank you for the opportunity to discuss these important issues with you, and I will be happy to answer any questions you may have.

Mr. BILIRAKIS. Thank you very much, Dr. Crawford.

Next we will hear from the Chairman of the Federal Trade Commission, Mr. Timothy Muris. Please proceed, sir.

STATEMENT OF HON. TIMOTHY J. MURIS

Mr. MURIS. Thank you very much, Mr. Chairman, and thank you for holding this hearing and for inviting me to testify.

I am pleased to appear today to testify on behalf of the Commission regarding competition in the pharmaceutical industry and, in particular, to discuss our study of generic drug entry prior to patent expiration. Let me address two issues briefly: our enforcement agenda, which influenced our study and the themes of the study that the Commission issued in July of this year.

First, the Commission has challenged conduct by firms that allegedly have gamed the Hatch-Waxman framework to deter or delay generic competition. Our first generation of such cases involved agreements through which a brand-name drug manufacturer allegedly paid a generic drug manufacturer not to enter and compete. It used the generic's rights under Hatch-Waxman to impede entry by other generic competitors.

Our second generation of enforcement activities has involved allegations that individual brand-name manufacturers have acted to delay generic competition by using the Hatch-Waxman provision that prohibits the FDA from approving a generic applicant for 30 months under certain circumstances. Brand-name drug manufacturers may sometimes act strategically to obtain more than one 30-month stay of FDA approval of a particular generic drug. We recently took action against Biovail Corporation for engaging in this type of activity for its drug product Tiazac, which is used to treat high blood pressure and chronic chest pain.

Next, let me briefly discuss our study. The study was prompted by several factors, including cases such as those I just discussed, a request from Representative Waxman to look into these issues, and, of course, the large amounts we spend on pharmaceuticals.

Looking at the timeframe from 1992 through 2000, the study asks whether and how generic drug companies entered and competed against brand-name drug manufacturers before the patents expired. An increasing number of generics have sought to enter before the expiration of patents. In all, the study examined the 104 brand-name drug products in which generic applicants sought entry prior to patent expiration between 1992 and 2000.

As we have heard in today's opening statements, under Hatch-Waxman the brand-name companies are required to list patents that claim each brand-name drug in the Orange Book. A generic applicant then may certify that its product does not infringe or that the patents are invalid. If, in response, the brand-name manufacturer sues the generic applicant for patent infringement, the FDA may not approve the generic application until a court's determination of invalidity or non-infringement or 30 months from the receipt of the certification.

We found that 30 months historically has approximated the time necessary for FDA review and approval of the generics application, as well as the time necessary for a district court to resolve the patent infringement litigation. Thus, in most circumstances it does not appear that the 30-month stay itself has a significant potential to delay generic entry.

However, there have been eight brand-name drug products in which the brand-name manufacturers have been able to obtain

more than one 30-month stay. This has cost additional delay of FDA approval of the generic application from 4 to 40 months beyond the initial 30 months. Our study recommends a limit of one automatic 30-month stay per drug product per generic application to resolve infringement disputes over patents that were listed in the Orange Book prior to the filing of the generic application.

We also researched the circumstances surrounding another Hatch-Waxman provision that awards 180 days of market exclusivity to the first generic applicant to apply to enter before patent expiration. During this 180 days, the FDA may not approve a subsequent generic application for the same drug product. This provision provides an economic incentive for companies to challenge patent validity and design around patents to find alternative, non-infringing forms of patented drugs.

The data in the study suggests that generic applicants have mostly brought appropriate patent challenges. For the drug products covered by the FTC study, generic applicants prevailed in nearly 75 percent of the patent litigation resolved by court decision.

Sometimes, however, the litigation is settled and not litigated to conclusion. Our study found 14 final settlement agreements that at the time they were executed had the potential to “park” the first generic applicant’s 180-day exclusivity for some period of time and, thus, possibly to prevent subsequent generic entry.

Such agreements may be pro-competitive, they may be competitive-neutral, and, of course, they may be anti-competitive. Because they have the potential to raise antitrust issues, we support the Drug Competition Act of 2001, S. 754, introduced by Senator Leahy, as reported by the Committee on the Judiciary, which would require the filing of these type of agreements with the FTC and the Department of Justice.

We will continue to be active to protect consumers from anti-competitive practices that inflate drug prices. Indeed, since my arrival as Chairman 16 months ago, we have increased our resources in health care by 50 percent, the vast majority of that dealing with pharmaceuticals.

We look forward to working closely with the subcommittee, as we have in the past, to meet this goal. I want to thank you, Mr. Chairman, on behalf of the Commission for your support of our work.

[The prepared statement of Hon. Timothy J. Muris follows:]

PREPARED STATEMENT OF HON. TIMOTHY J. MURIS, CHAIRMAN, FEDERAL TRADE COMMISSION

I. INTRODUCTION

Mr. Chairman, I am Timothy J. Muris, Chairman of the Federal Trade Commission. I am pleased to appear before the Subcommittee today to testify on behalf of the Commission regarding competition in the pharmaceutical industry.¹

Advances in the pharmaceutical industry continue to bring enormous benefits to Americans. Because of pharmaceutical innovations, a growing number of medical conditions often can be treated more effectively with drugs and drug therapy than with alternative means (*e.g.*, surgery). The development of new drugs is risky and costly, however, which increases the prices of prescription drugs. Expenditures on pharmaceutical products continue to grow. The growth of prescription drug spending

¹ The written statement represents the views of the Federal Trade Commission. My oral presentation and responses are my own and do not necessarily reflect the views of the Commission or of any other Commissioner.

at retail outlets has “exceeded that of other health services by a wide margin, increasing 17.3 percent in 2000, the sixth consecutive year of double-digit growth.”² Pharmaceutical expenditures are thus a concern not only to individual consumers, but also to government payers, private health plans, and employers.

To address the issue of escalating drug expenditures, and to ensure that the benefits of pharmaceutical innovation would continue, Congress passed the Hatch-Waxman Amendments³ (“Hatch-Waxman” or “the Amendments”) to the Food, Drug and Cosmetic Act (“FDC Act”).⁴ Hatch-Waxman established a regulatory framework that sought to balance incentives for continued innovation by research-based pharmaceutical companies and opportunities for market entry by generic drug manufacturers.⁵ Without question, Hatch-Waxman has increased generic drug entry. The Congressional Budget Office estimates that, by purchasing generic equivalents of brand-name drugs, consumers saved \$8-10 billion on retail purchases of prescription drugs in 1994 alone.⁶ With patents set to expire within the next four years on brand-name drugs having combined U.S. sales of almost \$20 billion,⁷ the already substantial savings are likely to increase dramatically.

Yet, in spite of this remarkable record of success, the Amendments have also been subject to some abuse. Although many drug manufacturers—including both brand-name companies and generics—have acted in good faith, others have attempted to “game” the system, securing greater profits for themselves without providing a corresponding benefit to consumers. This testimony will describe the Commission’s past and present response to these anticompetitive efforts.

The Commission has pursued numerous antitrust enforcement actions affecting both brand-name and generic drug manufacturers.⁸ In addition, the Commission recently released a study entitled “Generic Drug Entry Prior to Patent Expiration” (“FTC Study”). That study examines whether the conduct that the FTC has challenged represented isolated instances or is more typical of business practices in the pharmaceutical industry, and whether certain provisions of Hatch-Waxman are susceptible to strategies to delay or deter consumer access to generic alternatives to brand-name drug products.⁹ The Commission has gained expertise regarding competition in the pharmaceutical industry through other means as well. The Commission staff has conducted empirical analyses of competition in the pharmaceutical industry, including in-depth studies by the staff of the Bureau of Economics.¹⁰ The Commission’s efforts have included filing comments with the Food and Drug Administration (“FDA”) regarding the competitive aspects of Hatch-Waxman implementa-

²K. Levit, C. Smith, C. Cowan, H. Lazenby & A. Martin, “Inflation Spurs Health Spending in 2000,” 21:1 *Health Affairs* 179 (2002), citing data from the Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group, of which the authors are members.

³Drug Price Competition and Patent Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended 21 U.S.C. § 355 (1994)).

⁴21 U.S.C. § 301 *et seq.*

⁵See *infra* note 14 and accompanying text. The Amendments also were intended to encourage pharmaceutical innovation through patent term extensions.

⁶Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998) (“CBO Study”), available at <<http://www.cbo.gov/showdoc.cfm?index=655&sequence=0>>.

⁷*Id.* at 3.

⁸See, e.g., *Biovail Corp. and Elan Corp. PLC*, Dkt. No. C-4057 (Aug. 20, 2002) (consent order); *Biovail Corp.*, Dkt. No. C-4060 (Oct. 2, 2002) (consent order); *FTC v. Mylan Laboratories, Inc. et al.*, 62 F. Supp. 2d 25 (D.D.C. 1999); *Roche Holding Ltd.*, 125 F.T.C. 919 (1998) (consent order); *Ciba-Geigy Ltd.*, 123 F.T.C. 842 (1997) (consent order).

⁹Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002), available at <<http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>>.

¹⁰Bureau of Economics Staff Report, Federal Trade Commission, *The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change* (Mar. 1999), available at <<http://www.ftc.gov/reports/pharmaceutical/drugrep.pdf>>; David Reiffen and Michael R. Ward, *Generic Drug Industry Dynamics*, Bureau of Economics Working Paper No. 248 (Feb. 2002) (“Reiffen and Ward”), available at <<http://www.ftc.gov/be/econwork.htm>>.

tion,¹¹ as well as previous testimony before Congress.¹² Furthermore, individual Commissioners have addressed the subject of pharmaceutical competition before a variety of audiences, both to solicit input from affected parties and to promote discussion about practical solutions.¹³

After reviewing the relevant Hatch-Waxman provisions, this testimony will address the Commission's vigorous enforcement of the antitrust laws with respect to generic drug competition. These efforts have entailed several types of conduct relating to certain Hatch-Waxman provisions. One type of conduct involves allegedly anticompetitive settlements between brand-name companies and generics. Because the Commission became aware of and challenged such settlements first, this testimony refers to those matters as "first-generation litigation." Other, more recent types of conduct, such as allegedly improper Orange Book listings and potentially anticompetitive settlements between generic manufacturers themselves, are the subject of the Commission's "second-generation actions."

Next, the testimony will address the Commission's industry-wide study of generic drug entry prior to patent expiration. An understanding of the Commission's cases in this area will provide the framework for the issues that the Commission examined in this study.

II. REGULATORY BACKGROUND: THE HATCH-WAXMAN DRUG APPROVAL PROCESS

A. The Hatch-Waxman Balance

The stated purpose of Hatch-Waxman is to "make available more low cost generic drugs."¹⁴ The concern that the FDA's lengthy drug approval process was unduly delaying market entry by generic versions of brand-name prescription drugs motivated Congress's passage of the Amendments. Because a generic drug manufacturer was required to obtain FDA approval before selling its product, and could not begin the approval process until any conflicting patents on the relevant brand-name product expired, the FDA approval process essentially functioned to extend the term of the brand-name manufacturer's patent. To correct this problem, Congress provided in the Amendments that certain conduct related to obtaining FDA approval, which would otherwise constitute patent infringement, would be exempted from the patent laws.

Congress continued to regard patent protection, however, as critical to pharmaceutical innovation and an important priority in its own right. Hatch-Waxman thus represented a compromise: an expedited FDA approval process to speed generic entry balanced by additional intellectual property protections to ensure continuing innovation. As one federal appellate judge explained, the Amendments "emerged from Congress's efforts to balance two conflicting policy objectives: to induce brand-name pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market."¹⁵

¹¹ *FDA: Citizen Petition*, Comment of the Staff of the Bureau of Competition and of the Office of Policy Planning of the Federal Trade Commission Before the Food and Drug Administration (Mar. 2, 2000), available at <<http://www.ftc.gov/be/v000005.pdf>> (recommending modifications to the FDA's Proposed Rule on citizen petitions intended to discourage anticompetitive abuses of the FDA's regulatory processes); *FDA: 180-Day Marketing Exclusivity for Generic Drugs*, Comment of the Staff of the Bureau of Competition and of the Office of Policy Planning of the Federal Trade Commission Before the Food and Drug Administration (Nov. 4, 1999) ("Marketing Exclusivity Comment"), available at <<http://www.ftc.gov/be/v990016.htm>> (recommending that the FDA's Proposed Rule on 180-day marketing exclusivity be modified to limit exclusivity to the first ANDA filer and to require filing of patent litigation settlement agreements).

¹² Testimony of the Federal Trade Commission before the Committee on Commerce, Science, and Transportation, United States Senate, *Competition in the Pharmaceutical Industry* (Apr. 23, 2002), available at <<http://www.ftc.gov/os/2002/04/pharmtestimony.htm>>; Testimony of the Federal Trade Commission before the Committee on the Judiciary, United States Senate, *Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements* (May 24, 2001), available at <<http://www.ftc.gov/os/2001/05/pharmtstmy.htm>>.

¹³ See, e.g., Sheila F. Anthony, *Riddles and Lessons from the Prescription Drug Wars: Antitrust Implications of Certain Types of Agreements Involving Intellectual Property* (June 1, 2000), available at <<http://www.ftc.gov/speeches/anthony/sfip000601.htm>>; Thomas B. Leary, *Antitrust Issues in Settlement of Pharmaceutical Patent Disputes* (Nov. 3, 2000), available at <<http://www.ftc.gov/speeches/leary/learypharma.htm>>; Thomas B. Leary, *Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part II* ("Part II") (May 17, 2001), available at <http://www.ftc.gov/speeches/leary/learypharmaceutical_settlement.htm>; Timothy J. Muris, *Competition and Intellectual Property Policy: The Way Ahead*, at 5-6 (Nov. 15, 2001), available at <<http://www.ftc.gov/speeches/muris/intellectual.htm>>.

¹⁴ H.R. Rep. No. 98-857, pt. 1, at 14 (1984), reprinted in 1984 U.S.C.A.N. 2647, 2647.

¹⁵ *Abbott Labs. v. Young*, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting) (citations omitted).

Pursuant to the FDC Act, a brand-name drug manufacturer seeking to market a new drug product must first obtain FDA approval by filing a New Drug Application (“NDA”). At the time the NDA is filed, the NDA filer must also provide the FDA with certain categories of information regarding patents that cover the drug that is the subject of its NDA.¹⁶ Upon receipt of the patent information, the FDA is required to list it in an agency publication entitled “Approved Drug Products with Therapeutic Equivalence,” commonly known as the “Orange Book.”¹⁷

Rather than requiring a generic manufacturer to repeat the costly and time-consuming NDA process, the Amendments permit the company to file an Abbreviated New Drug Application (“ANDA”), which references data that the “pioneer” manufacturer has already submitted to the FDA regarding the brand-name drug’s safety and efficacy. Under the ANDA process, an applicant must demonstrate that the generic drug is “bioequivalent” to the relevant brand-name product.¹⁸ The ANDA must contain, among other things, a certification regarding each patent listed in the Orange Book in conjunction with the relevant NDA.¹⁹ One way to satisfy this requirement is to provide a “Paragraph IV certification,” asserting that the patent in question is invalid or not infringed.²⁰

Filing a Paragraph IV certification potentially has significant regulatory implications, as it is a prerequisite to the operation of two provisions of the statute. The first of these is the automatic “30-month stay” protection afforded to patent holders and the NDA filer—most typically, brand-name companies. An ANDA filer that makes a Paragraph IV certification must provide notice to both the patent holder and the NDA filer, including a detailed statement of the factual and legal basis for the ANDA filer’s assertion that the patent is invalid or not infringed.²¹ Once the ANDA filer has provided such notice, a patent holder wishing to take advantage of the statutory stay provision must bring an infringement suit within 45 days.²² If the patent holder does not bring suit within 45 days, the FDA may approve the ANDA as soon as other regulatory conditions are fulfilled.²³ If the patent holder does bring suit, however, the filing of that suit triggers an automatic 30-month stay of FDA approval of the ANDA.²⁴ During this period, unless the patent litigation is resolved in the generic’s favor, the FDA cannot approve the generic product.

The second significant component of Hatch-Waxman is the “180-day period of exclusivity.” The Amendments provide that the first generic manufacturer to file an ANDA containing a Paragraph IV certification is awarded 180 days of marketing exclusivity, during which the FDA may not approve a potential competitor’s ANDA.²⁵ Through this 180-day provision, the Amendments provide an increased incentive for companies to challenge patents and develop alternative forms of patented drugs.²⁶ The 180-day period is calculated from the date of the first commercial marketing of the generic drug product or the date of a court decision declaring the patent invalid or not infringed, whichever is sooner.²⁷ The 180-day exclusivity period increases the economic incentives for a generic company to be the first to file an ANDA.²⁸ Of course, during the 180 days, the generic competes with the brand-name product. After the 180 days, subject to regulatory approvals and determination of the outcomes of any patent suits, other generics can enter the market.

B. Competitive Implications

The 30-month stay and the 180-day period of exclusivity were both parts of the Hatch-Waxman balance. The imposition of a 30-month stay of FDA approval of an eligible ANDA could forestall generic competition during that period of time. The 180-day period of exclusivity can, in some circumstances, limit the number of generic competitors during this 180-day period. Over the past few years the Commis-

¹⁶ 21 U.S.C. § 355(b)(1).

¹⁷ *Id.* at § 355(j)(7)(A).

¹⁸ *Id.* at § 355(j)(2)(A)(iv).

¹⁹ *Id.* at § 355(j)(2)(A)(vii).

²⁰ *Id.* at § 355(j)(2)(A)(vii)(IV).

²¹ *Id.* at § 355(j)(2)(B). Although the patent holder and the NDA filer are often the same person, this is not always the case. Hatch-Waxman requires that all patents that claim the drug described in an NDA be listed in the Orange Book. Occasionally, this requires an NDA filer to list a patent that it does not own.

²² *Id.* at § 355(j)(5)(B)(iii).

²³ *Id.* For example, the statute requires the ANDA applicant to establish bioequivalence. *Id.* at § 355(j)(2)(A)(iv).

²⁴ *Id.* at § 355(j)(5)(B)(iii).

²⁵ *Id.* at § 355(j)(5)(B)(iv).

²⁶ See *Granutech, Inc. v. Shalala*, 139 F.3d 889, 891 (4th Cir. 1998).

²⁷ 21 U.S.C. § 355(j)(5)(B)(iv).

²⁸ There has been litigation over what acts trigger the 180-day period of exclusivity. See FTC Study, *supra* note 9. This study is discussed in detail below.

sion has observed through its investigations, law enforcement actions, and industry-wide study that some brand-name and generic drug manufacturers may have “gamed” these two provisions, attempting to restrict competition beyond what the Amendments intended. The next section of this testimony discusses the Commission’s efforts to investigate vigorously and to prosecute such abuses.

III. PROMOTING COMPETITION THROUGH ANTITRUST ENFORCEMENT

A. *First-Generation FTC Litigation: Settlements Between Brand-Name Companies and Generic Applicants*

Studies of the pharmaceutical industry indicate that the first generic competitor typically enters the market at a significantly lower price than its brand-name counterpart, and gains substantial share from the brand-name product.²⁹ Subsequent generic entrants may enter at even lower prices and cause the earlier entrants to reduce their prices. These are precisely the procompetitive consumer benefits that the Amendments were meant to facilitate.

This competition substantially erodes the profits of brand-name pharmaceutical products. Although successful generic applicants are profitable, their gain is substantially less than the loss of profits by the brand-name product, because of the typical difference in prices between brand-name and generic products. As a result, both parties may have economic incentives to collude to delay generic entry. By blocking entry, the brand-name manufacturer may preserve monopoly profits. A portion of these profits, in turn, can be used to fund payments to the generic manufacturer to induce it to forgo the profits it could have realized by selling its product. Furthermore, by delaying the first generic’s entry—and with it, the triggering of the 180 days of exclusivity—the brand-name and first-filing generic firms can sometimes forestall the entry of other generics.

The Commission’s first-generation litigation focused on patent settlement agreements between brand-name companies and generic applicants that the Commission alleged had delayed the entry of one or more generic applicants. Of course, resolving patent infringement litigation through settlement can be efficient and procompetitive. Certain patent settlements between brand-name companies and generic applicants, however, drew the Commission’s attention when it appeared that their terms may have reduced competition through abuses of the Hatch-Waxman regime.

Two leading cases illustrate the Commission’s efforts in the area: *Abbott/Geneva* and *Hoechst/Andrx*. The first of these cases involved an agreement between Abbott Laboratories and Geneva Pharmaceuticals, Inc. relating to Abbott’s brand-name drug Hytrin. The Commission’s complaint alleged that Abbott paid Geneva approximately \$4.5 million per month to delay the entry of its generic Hytrin product, potentially costing consumers hundreds of millions of dollars a year.³⁰ The complaint further alleged that Geneva agreed not to enter the market with any generic Hytrin product—including a non-infringing product—until (1) final resolution of the patent infringement litigation involving Geneva’s generic Hytrin tablets, or (2) market entry by another generic Hytrin manufacturer. Geneva also allegedly agreed not to transfer its 180-day marketing exclusivity rights.

The second case involved an agreement between Hoechst Marion Roussel, Inc. and Andrx Corp. relating to Hoechst’s brand-name drug Cardizem CD. The Commission’s complaint alleged that Hoechst paid Andrx over \$80 million, during the pendency of patent litigation, to refrain from entering the market with its generic Cardizem CD product.³¹ As in the *Abbott/Geneva* case, the Commission’s complaint also asserted that the agreement called for Andrx, as the first ANDA filer, to use its 180-day exclusivity rights to impede entry by other generic competitors.

The Commission resolved both cases by consent order.³² The orders prohibit the respondent companies from entering into brand/generic agreements pursuant to

²⁹ See CBO Study, *supra* note 6; see generally Reiffen and Ward, *supra* note 10.

³⁰ *Abbott Laboratories*, Dkt. No. C-3945 (May 22, 2000) (consent order), complaint available at <<http://www.ftc.gov/os/2000/05/c3945complaint.htm>>; *Geneva Pharmaceuticals, Inc.*, Dkt. No. C-3946 (May 22, 2000) (consent order), complaint available at <<http://www.ftc.gov/os/2000/05/c3946complaint.htm>>.

³¹ *Hoechst Marion Roussel, Inc.*, Dkt. No. 9293 (May 8, 2001) (consent order), complaint available at <<http://www.ftc.gov/os/2000/03/hoechstandrxc.complaint.htm>>.

³² The consent order in *Abbott Laboratories* is available at <<http://www.ftc.gov/os/2000/03/abbot.do.htm>>. The consent order in *Geneva Pharmaceuticals* is available at <<http://www.ftc.gov/os/2000/03/genevad&o.htm>>. The consent order in *Hoechst/Andrx* is available at <<http://www.ftc.gov/os/2001/05/hoechstdo.pdf>>. In another matter, Schering-Plough, the Commission resolved all claims against one of three respondents, American Home Products (“AHP”), by issuing a final consent order. *Schering-Plough Corp.*, Dkt. No. 9297 (consent order as to AHP issued Apr. 2, 2002), available at <<http://www.ftc.gov/os/2002/04/scheringplough-do.htm>>.

which a generic company that is the first ANDA filer with respect to a particular drug agrees not to (1) enter the market with a non-infringing product, or (2) transfer its 180-day marketing exclusivity rights. In addition, the orders require the companies to obtain court approval for any agreements made in the context of an interim settlement of a patent infringement action that provide for payments to the generic to stay off the market, with advance notice to the Commission to allow it time to present its views to the court. The orders also require advance notice to the Commission before the respondents can enter into such agreements in non-litigation contexts.

Although each case turns on its own specific facts, these cases highlight the Commission's concern about settlements whose primary effect appears to be to delay generic entry, leading to less vigorous competition and higher prices for consumers. Of course, not all settlements are problematic. The Commission has not attempted to provide a comprehensive list of potentially objectionable settlement provisions. However, it is possible to identify from the Commission's reported matters a few provisions that, within the Hatch-Waxman context, have drawn antitrust scrutiny. These include:

(1) *Provisions that provide for "reverse" payments.* "Reverse" payments (*i.e.*, payments from the patent holder to the alleged infringer) may merit antitrust scrutiny because they may represent an anticompetitive division of monopoly profits.

(2) *Provisions that restrict the generic's ability to enter with non-infringing products.* Such provisions can extend the boundaries of the patent monopoly without providing any additional public disclosure or incentive to innovate, and therefore have the potential to run afoul of the principles of antitrust law.³³

(3) *Provisions that restrict the generic's ability to assign or waive its 180-day marketing exclusivity rights.* Because a second ANDA filer may not enter the market until the first filer's 180-day period of marketing exclusivity has expired, restrictions on assignment or waiver of the exclusivity period can function as a bottleneck, potentially delaying subsequent generic entry for an extended period.³⁴

B. Second-Generation FTC Actions: Improper Orange Book Listings

1. *In re Buspirone*—A principal focus of the Commission's second-generation activities has been improper Orange Book listings.³⁵ Unlike the settled cases discussed above, which involved alleged collusion between private parties, an improper Orange Book listing strategy involves unilateral abuse of the Hatch-Waxman process itself to restrain trade. Such conduct has raised *Noerr-Pennington* antitrust immunity issues, an area of longstanding Commission interest.

The *Noerr* doctrine³⁶ provides antitrust immunity for individuals "petitioning" government. While the *Noerr* doctrine is an important limitation on the antitrust laws that protects the right of individuals to communicate with government entities, some courts have interpreted the doctrine too broadly in ways that are inconsistent with Supreme Court precedent.

To address the concern that the *Noerr* doctrine was being interpreted too expansively, a *Noerr-Pennington* Task Force of Commission staff began work in June 2001. One of the objectives of the Task Force was to examine certain aspects of the *Noerr* doctrine, such as the scope of "petitioning" conduct and the continuing existence of a misrepresentation exception to *Noerr* immunity.

One of the first potential abuses the Task Force considered was the improper listing of patents in the FDA's Orange Book. Pursuant to current policy, the FDA does not review patents presented for listing in the Orange Book to determine whether

³³The case against the other two respondents is in litigation before the Commission. See *Schering-Plough Corp., et al.*, Dkt. No. 9297 (Initial Decision) (July 2, 2002), available at <<http://www.ftc.gov/os/2002/07/scheringinitialdecisionp1.pdf>>.

³⁴*Cf. Brulotte v. Thys Co.*, 379 U.S. 29, 33 (1964) (holding that "enlarg[ing] the monopoly of the patent" by collecting post-expiration royalties constitutes patent misuse).

³⁵*But see* Leary, Part II, *supra* note 13, at 7 (arguing that agreements regarding waiver of 180-day exclusivity period may have no anticompetitive effect absent reverse payment).

³⁶The Commission first raised concerns about the potential anticompetitive impact of improper Orange Book listings in *American Bioscience, Inc. v. Bristol-Myers Squibb Co., et al.*, Dkt. No. CV-00-08577 (C.D. Cal. Sept. 7, 2000). See Federal Trade Commission Brief as *amicus curiae*, available at <<http://www.ftc.gov/os/2000/09/amicusbrief.pdf>>. In that case, the parties sought court approval of a settlement containing a specific factual finding that Bristol-Myers was required to list American Bioscience's patent of Bristol-Myers's branded drug Taxol in the Orange Book. The Commission was concerned that the court's approval of the settlement would amount to a judicial finding that the patent met the statutory requirements for listing in the Orange Book and would prejudice parties who might later challenge the listing.

³⁷The *Noerr* doctrine was first articulated as an interpretation of the Sherman Act in *Eastern R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961), and *United Mine Workers of America v. Pennington*, 381 U.S. 657 (1965).

they do, in fact, claim the drug product described in the relevant NDA.³⁷ Instead, the FDA takes at face value the declaration of the NDA filer that the listing is appropriate. As a result, an NDA filer acting in bad faith can successfully list patents that do not satisfy the statutory listing criteria. Once listed in the Orange Book, these patents have the same power to trigger a 30-month stay of ANDA approval as any listed patent, thereby delaying generic entry and potentially costing consumers millions, or even billions, of dollars without valid cause.

In January of this year, lawsuits relating to Bristol-Myers's alleged monopolization through improper listing of a patent on its brand-name drug BuSpar³⁸ presented the Commission with an opportunity to clarify the *Noerr* doctrine in a way that might have a significant impact on the Commission's ongoing pharmaceutical cases. Specifically, plaintiffs alleged that, through fraudulent filings with the FDA, Bristol-Myers caused that agency to list the patent in question in the Orange Book, thereby blocking generic competition with its BuSpar product, in violation of Section 2 of the Sherman Act.³⁹

Bristol-Myers responded to these allegations by filing a motion to dismiss that raised, principally, a claim of *Noerr-Pennington* immunity. Given the importance of the issue to competition in the pharmaceutical industry, as well as to the Commission's ongoing investigations, the Commission filed an amicus brief opposing the motion to dismiss.⁴⁰ On February 14, 2002, the court issued an opinion denying Bristol-Myers's immunity claim and accepting most of the Commission's reasoning on the *Noerr-Pennington* issue.⁴¹

In light of the *Buspirone* decision, the *Noerr-Pennington* doctrine may not prove as large an obstacle to using the antitrust laws to remedy improper Orange Book filings as some may have anticipated. It is worth noting, and indeed emphasizing, that *Buspirone* does not mean that all improper Orange Book filings will give rise to antitrust liability. Any antitrust liability must be predicated on a clear showing of a violation of substantive antitrust law. *Buspirone* makes it clear, however, that Orange Book filings are not *immune* from those laws or *exempt* from their scrutiny.

2. *Biovail (Tiazac)*—Last week, the Commission announced that it had issued a consent order against Biovail Corporation,⁴² settling charges that Biovail illegally acquired an exclusive patent license and wrongfully listed that patent in the Orange Book for the purpose of blocking generic competition to its brand-name drug Tiazac. This was the Commission's first enforcement action to remedy the effects of an allegedly improper, anticompetitive Orange Book listing.

Prior to the events giving rise to the Commission's complaint, Biovail already had triggered a 30-month stay of FDA final approval of Andrx's generic Tiazac product, by commencing an infringement lawsuit against Andrx. Andrx prevailed in the courts, however, so that the stay would have been lifted by February 2001. According to the Commission's complaint,⁴³ Biovail, in anticipation of pending competition from Andrx, undertook a series of anticompetitive actions to trigger a new stay and maintain its Tiazac monopoly. Just before the stay was to terminate, Biovail acquired exclusive rights to a newly issued patent from a third party and listed that patent in the Orange Book as claiming Tiazac—thereby requiring Andrx to re-certify

³⁷See 21 C.F.R. § 314.53(f); see also Abbreviated New Drug Application Regulations—Patent and Exclusivity Provisions, 59 Fed. Reg. 50338, 50343 (1994) (“FDA does not have the expertise to review patent information. The agency believes that its resources would be better utilized in reviewing applications rather than reviewing patent claims.”); Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28872, 28910 (1989) (“In deciding whether a claim of patent infringement could reasonably be asserted...the agency will defer to the information submitted by the NDA applicant.”).

³⁸*In re Buspirone Patent Litigation/In re Buspirone Antitrust Litigation*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002) (“*In re Buspirone*”). Some of the same plaintiffs previously had brought suit under the FDC Act, requesting that the court issue an order compelling Bristol-Myers to delist the objectionable patent. Although plaintiffs prevailed at the district court level, the Federal Circuit reversed that decision, holding that the FDC Act did not provide a private right of action to compel de-listing of a patent from the Orange Book. See *Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323, 1331-32 (Fed. Cir. 2001).

³⁹15 U.S.C. § 2.

⁴⁰Memorandum of Law of *Amicus Curiae* Federal Trade Commission in Opposition to Defendant's Motion to Dismiss, available at <<http://www.ftc.gov/os/2002/01/busparbrief.pdf>>. (The Commission argued that Orange Book filings are not “petitioning activity” immune from antitrust scrutiny.)

⁴¹*In re Buspirone*, *supra* note 38.

⁴²*Biovail Corp.*, *supra* note 8.

⁴³The Commission's complaint against Biovail is available at <<http://www.ftc.gov/os/2002/04/biovailcomplaint.htm>>.

to the FDA and opening the door to Biovail's suit against Andrx for infringement of the new patent and commencement of a second 30-month stay.

The Commission's complaint alleged that Biovail's patent acquisition, wrongful Orange Book listing, and misleading conduct before the FDA were acts in unlawful maintenance of its Tiazac monopoly, in violation of Section 5 of the Federal Trade Commission Act⁴⁴ ("FTC Act"), and that the acquisition also violated Section 7 of the Clayton Act⁴⁵ and Section 5 of the FTC Act.

The consent order requires Biovail to divest the exclusive rights to their original owner with certain exceptions; to achieve dismissal with prejudice of any and all claims relating to enforcement of the patent in relation to Tiazac; and to refrain from any action that would trigger another 30-month stay on generic Tiazac entry. Further, the order prohibits Biovail from unlawfully listing patents in the Orange Book and requires Biovail to give the Commission prior notice of acquisitions of patents that it will list in the Orange Book for Biovail's FDA-approved products. These measures should not only remedy Biovail's allegedly unlawful conduct, but also send a strong message that the Commission will act decisively to eliminate anticompetitive practices in the pharmaceutical industry.

C. Settlements Between Generic Manufacturers

Although agreements between first and second generic entrants have attracted significantly less attention to date, they too can raise competitive concerns and may draw antitrust scrutiny. As in the case of agreements between brand-name companies and generic applicants, the economic incentives to collude can be strong. Studies indicate that the first generic typically enters the market at 70 to 80 percent of the price of the corresponding brand⁴⁶ and rapidly secures as much as a two-thirds market share. The second generic typically enters at an even lower price and, like the first, rapidly secures market share. Collusion between the generic firms can thus be a means of preventing price erosion in the short term, though it may become substantially less feasible if subsequent ANDAs are approved and additional competitors enter the market.

In August 2002, the Commission issued a consent order against two generic drug manufacturers to resolve charges that they entered into an agreement that unreasonably reduced competition in the market for a generic anti-hypertension drug.⁴⁷ According to the Commission's complaint, Biovail Corporation (Biovail) and Elan Corporation PLC (Elan) agreed not to compete, in violation of the FTC Act. The complaint alleged that the companies' agreement substantially reduced their incentives to introduce competing 30 mg and 60 mg generic Adalat CC products, and that the agreement lacked any countervailing efficiencies.⁴⁸

The order, which has a ten-year term, remedies the companies' alleged anticompetitive conduct by requiring them to terminate the agreement and barring them from engaging in similar conduct in the future.⁴⁹ The order maintains commercial supply of the incumbent generic Adalat products while the companies unwind their agreement, and eliminates the anticompetitive obstacles to entry of a second 30 mg and a second 60 mg generic Adalat CC product.

IV. THE COMMISSION'S INDUSTRY-WIDE GENERIC DRUG COMPETITION STUDY

A. Background and Introduction

In light of the questions its various generic drug investigations raised, the Commission proposed an industry-wide study of generic drug competition in October 2000. The FTC Study focused solely on the procedures used to facilitate generic drug entry *prior to* expiration of the patent(s) that protect the brand-name drug product—that is, generic entry through the procedures involving Paragraph IV certifications.⁵⁰ The Commission undertook the study for three reasons:

(1) To determine whether alleged anticompetitive agreements that relied on certain Hatch-Waxman provisions were isolated instances or more typical, and whether particular provisions of the Amendments are susceptible to strategies to delay or deter consumer access to generic alternatives to brand-name drug products;

⁴⁴ 15 U.S.C. § 45.

⁴⁵ *Id.* at § 18.

⁴⁶ See CBO Study, *supra* note 6; Reiffen and Ward, *supra* note 10, at 22.

⁴⁷ *Biovail Corp. and Elan Corp. PLC*, *supra* note 8.

⁴⁸ The Commission's complaint against Biovail and Elan is available at <<http://www.ftc.gov/os/2002/08/biovalcomp.pdf>>.

⁴⁹ The consent order in the *Biovail/Elan* matter is available at <<http://www.ftc.gov/os/2002/08/biovaldo.pdf>>.

⁵⁰ The FTC Study does not address other procedures for generic entry.

(2) To respond to Representative Henry Waxman's request for the Commission to "investigate and produce a study on the use of agreements between and among pharmaceutical companies and potential generic competitors and any other strategies that may delay generic drug competition throughout the U.S."; and

(3) To ensure that there are no roadblocks in the way of generic competition for the substantial sales volume of brand-name drug products coming off patent in the next several years.⁵¹ Brand-name companies seeking to protect the sales of brand-name drugs may have an incentive and ability to enter into agreements with would-be generic competitors, or engage in other types of activities, that would slow or thwart the entry of competing generic drug products.

In April 2001, the Commission received clearance from the Office of Management and Budget ("OMB") to conduct the study.⁵² The Commission issued nearly 80 special orders—pursuant to Section 6(b) of the FTC Act⁵³—to brand-name companies and to generic drug manufacturers, seeking information about certain practices that were outlined in the Federal Register notices that preceded OMB clearance to pursue the study.⁵⁴ The Commission staff focused the special orders on brand-name drug products that were the subject of Paragraph IV certifications filed by generic applicants. Only those NDAs in which a generic applicant notified a brand-name company with a Paragraph IV certification after January 1, 1992, and prior to January 1, 2001, were included in the FTC Study. The selection criteria resulted in 104 drug products, as represented by NDAs filed with the FDA, within the scope of the study and included so-called "blockbuster" drugs such as Capoten, Cardizem CD, Cipro, Claritin, Lupron Depot, Neurontin, Paxil, Pepcid, Pravachol, Prilosec, Procardia XL, Prozac, Vasotec, Xanax, Zantac, Zocor, Zoloft, and Zyprexa.

Responses from the 28 brand-name companies and nearly 50 generic applicants generally were completed by the end of 2001. The Commission staff compiled the information received to provide a factual description of how the 180-day marketing exclusivity and 30-month stay provisions affect the timing of generic entry prior to patent expiration. The FTC Study did not provide an antitrust analysis of each of the types of agreements submitted, nor did it examine other issues involved in the debate over generic drugs, such as bioequivalence or the appropriate length of patent restorations under Hatch-Waxman.

B. Findings: Litigation Frequency and Outcomes

The FTC Study sought to determine the frequency with which brand-name companies have triggered the 30-month stay provision by suing generic applicants for patent infringement within the required 45-day period. For 72 percent of drug products the study covered, brand-name companies initiated patent infringement litigation against the first generic applicant. There was no suit in the other 28 percent, and the FDA has approved most of the generic products, thus allowing generic entry to occur.

In 70 percent of the cases (53 of the 75 drug products) in which the brand-name company sued the first generic applicant, either there has been a court decision (30 of the 53 drug products) or the parties have agreed to a final settlement without a court decision on the merits of the patent infringement lawsuit (20 of the 53 drug products).⁵⁵ In the other 30 percent of the cases (22 of the 75 drug products), a district court had not yet ruled as of June 1, 2002.

Of all the patent infringement cases (with the first generic applicant) in which a court had rendered a decision as of June 1, 2002, generic applicants prevailed in 73 percent of the cases (22 out of 30) and brand-name companies prevailed in 27 percent (8 out of 30). Of the decisions favoring the first or any subsequent generic applicant, there were slightly more non-infringement decisions (14) than patent invalidity decisions (11). The U.S. Court of Appeals for the Federal Circuit overturned district court decisions of patent invalidity for drug products in this study in only eight percent of cases.

In 62 percent of the cases involving litigation with the first and second generic applicants, brand-name companies initiated patent litigation in just five federal judicial districts—the District of New Jersey, the Southern District of New York, the Southern District of Indiana, the Northern District of Illinois, and the Southern District of Florida.

⁵¹ National Institute for Health Care Management, "Prescription Drugs and Intellectual Property Protection" at 3 (Aug. 2000).

⁵² The Commission was required to obtain OMB clearance before it could begin the study because the number of special orders to be sent triggered the requirements of the Paperwork Reduction Act of 1995, 44 U.S.C. Ch. 35, as amended.

⁵³ 15 U.S.C. § 46(b).

⁵⁴ See 65 Fed. Reg. 61334 (Oct. 17, 2000); 66 Fed. Reg. 12512 (Feb. 27, 2001).

⁵⁵ There were three additional suits that had other resolutions.

C. Findings: Orange Book Patent Listing Practices

The 30-month stay provision of the Amendments protects brand-name companies beyond their existing intellectual property rights. It has received increased attention because it can have a significant impact on market entry by generic drugs. Since 1998, two new phenomena appear to be emerging in relation to patent listing practices that affect patent litigation: (1) an increase in the number of patents listed in the Orange Book for “blockbuster” drug products; and (2) the listing of patents after an ANDA has been filed for the particular drug product.

The Commission found that, for drug products with substantial annual net sales, brand-name companies are suing generic applicants over more patents. Since 1998, for five of the eight “blockbuster” drug products for which the brand-name company filed suit against the first generic applicant, the brand-name company alleged infringement of three or more patents. In comparison, in only one of the nine “blockbuster” suits filed before 1998 by a brand-name company against the first generic applicant did the complaint allege infringement of three or more patents.

In the future, patent infringement litigation brought by brand-name companies against generic applicants that have filed ANDAs with Paragraph IV certifications may take longer to resolve. The data suggest that cases involving multiple patents take longer than those involving fewer patents. As of June 1, 2002, for six out of the seven cases that were pending for more than 30 months before a decision from a district court, the brand-name company has alleged infringement of three or more patents.

By the timely listing of additional patents in the Orange Book after a generic applicant has filed its ANDA (“later-issued patents”), brand-name companies can obtain additional 30-month stays of FDA approval of the generic applicant’s ANDA. In eight instances, brand-name companies have listed later-issued patents in the Orange Book after an ANDA has been filed for the drug product. For those eight drug products, the additional delay of FDA approval (beyond the first 30 months) ranged from four to 40 months. In all of the four cases so far with a court decision on the validity or infringement of a later-issued patent, the patent has been found either invalid or not infringed by the ANDA.

Moreover, several of the later-issued patents in the Orange Book raise questions about whether the FDA’s patent listing requirements have been met. For example, several of the later-issued patents do not appear to claim the approved drug product or an approved use of the drug. The FTC Study describes three categories of patents that raise significant listability questions—*i.e.*, issues concerning whether the listed patents fall within the statutorily defined class. These categories include (1) patents that may not be considered to claim the drug formulation or method of use approved through the NDA; (2) product-by-process patents that claim a drug product produced by a specific process; and (3) patents that may constitute double-patenting because they claim subject matter that is obvious in view of the claims of another patent obtained by the same person.

D. Recommendations: The 30-Month Stay Provision

To reduce the possibility of abuse of the 30-month stay provision, the Commission recommended in its study that only one 30-month stay be permitted per drug product per ANDA to resolve infringement disputes over patents listed in the Orange Book prior to the filing date of the generic applicant’s ANDA. This should eliminate most of the potential for improper Orange Book listings to generate unwarranted 30-month stays. One 30-month stay period alone has historically approximated the time necessary for FDA review and approval of the generic applicant’s ANDA⁵⁶ or a district court decision on the patent infringement litigation that caused the 30-month stay. Thus, it does not appear that, on average, one 30-month stay provision per drug product per ANDA would have a significant potential to delay generic entry beyond the time already necessary for FDA approval of the generic applicant’s ANDA or a district court decision in the relevant litigation.

Limiting brand-name drug companies to one 30-month stay per drug product per ANDA is likely to eliminate most problems related to potentially improper Orange Book listings. Nonetheless, the Commission notes that there is no private right of action to challenge an improper listing, nor does the FDA review the propriety of patent listings.⁵⁷ The lack of a mechanism to review or delist patents may have real-world consequences. For example, the Commission is aware of at least a few instances in which a 30-month stay was generated solely by a patent that raised legitimate listability questions. One proposal to deal with this problem has been to

⁵⁶ FDA approval of ANDAs submitted by first generic applicants who were not sued by the brand-name company took, on average, 25.5 months from the ANDA filing date.

⁵⁷ See *supra* note 37 and accompanying text.

establish an administrative procedure through which generic applicants could obtain substantive FDA review of listability. At a minimum, it appears useful for the FDA to clarify its listing requirements as the FTC Study suggests. Another remedy that may warrant consideration would be to permit a generic applicant to raise listability issues as a counterclaim in the context of patent infringement litigation that the brand-name company already initiated in response to a Paragraph IV notice from the generic applicant. A challenge limited to a counterclaim would avoid generating additional litigation.

One minor change to the patent statute, which would clarify when brand-name companies can sue generic applicants for patent infringement, would ensure that brand-name companies have recourse to the courts to protect their intellectual property rights in later-issued patents. To do this, Congress may wish to overrule a recent district court decision, *Allergan, Inc. v. Alcon Labs, Inc.*, 200 F. Supp. 2d 1219 (C.D. Cal. 2002), which questions the rights of brand-name companies to sue for patent infringement regarding patents obtained or listed after an ANDA with a Paragraph IV certification has been filed.

E. Findings: Patent Settlements and the 180-Day Marketing Exclusivity

Certain patent settlement agreements between brand-name companies and potential generic competitors have received antitrust scrutiny in recent years because not only might they affect when the generic applicant may begin commercial marketing, but they also may affect when the FDA can approve subsequent generic applicants after the first generic applicant's 180-day exclusivity runs. Parties have debated whether these settlements increased or harmed consumer welfare. Twenty final⁵⁸ and four interim⁵⁹ agreements that settled litigation between the brand-name company and the first generic applicant were produced in response to the FTC's special orders.

The final patent settlements can be classified into three categories:

- (1) Nine of these settlements contained a provision by which the brand-name company, as one part of the settlement, paid the generic applicant (settlements involving "brand payments");
- (2) Seven of the 20 settlements involved the brand-name company licensing the generic applicant to use the patents for the brand-name drug product prior to patent expiration; and
- (3) Two of the settlements allowed the generic applicant to market the brand-name drug product as a generic product, under the brand-name company's NDA but not under not the generic applicant's own ANDA.⁶⁰

Fourteen of the final settlements with the first generic applicant had the potential to "park" the 180-day marketing exclusivity for some period of time such that the first generic applicant would not trigger the exclusivity, and thus FDA approval of any subsequent eligible generic applicant would be delayed. (If the 180-day exclusivity for the first generic applicant does not run, the FDA cannot approve subsequent eligible generic applicants.) The data from the FTC Study suggest, however, that the 180-day exclusivity provision by itself generally has not created a bottleneck to prevent FDA approval of subsequent eligible generic applicants.

In addition to the final settlements with the first generic applicant, brand-name companies entered final patent settlements with the second generic applicant in seven instances. In six of the seven, the brand-name company also had settled with the first generic applicant.

F. Recommendations: The 180-day Exclusivity Provision

To mitigate the possibility of abuse of the 180-day exclusivity provision, the FTC Study recommended that Congress pass the Drug Competition Act⁶¹ to require brand-name companies and first generic applicants to provide copies of certain agreements to the Federal Trade Commission and the Department of Justice. The Commission believes that review of these agreements by these agencies will help ensure that the 180-day provision is not manipulated in a way to delay entry of additional generic applicants.

Empirical research demonstrates that as additional generic competitors enter the market, generic prices decrease to lower levels, thus benefitting consumers. The

⁵⁸ One of these agreements is subject to litigation currently pending at the FTC. See *Schering-Plough Corp., et al.*, Dkt. No. 9297 (Initial Decision) (July 2, 2002) *supra* note 32.

⁵⁹ For three out of the four interim agreements, see *Abbott Laboratories*, Dkt. No. C-3945 (May 22, 2000) (consent order) (relating to two drug products, Hytrin tablets and Hytrin capsules); *Geneva Pharmaceuticals, Inc.*, Dkt. No. C-3946 (May 22, 2000) (consent order); and *Hoechst Marion Roussel, Inc.*, Dkt. No. 9293 (May 8, 2001) (consent order), all *supra* note 32.

⁶⁰ The remaining two settlements do not fit into any of these three categories.

⁶¹ S. 754, 107th Cong. (2001) (introduced by Sen. Leahy).

FTC Study makes three minor recommendations to ensure that, once a subsequent generic applicant is ready to market, the 180-day exclusivity is not a roadblock to that entrant's beginning commercial marketing. The recommendations are:

- (1) To clarify that "commercial marketing" includes the first generic applicant's marketing of the brand-name product;
- (2) To clarify that the decision of any court on the same patent being litigated by the first generic applicant constitutes a "court decision" sufficient to start the running of the 180-day exclusivity; and
- (3) To clarify that a court decision dismissing a declaratory judgment action for lack of subject matter jurisdiction constitutes a "court decision" sufficient to trigger the 180-day exclusivity.

V. CONCLUSION

Thank you for this opportunity to share the Commission's views on competition in the pharmaceutical industry. As you can see, the Commission has been and will continue to be very active in protecting consumers from anticompetitive practices that inflate drug prices. The Commission looks forward to working closely with the Subcommittee, as it has in the past, to ensure that competition in this critical sector of the economy remains vigorous. In keeping with this objective, the Commission will likewise endeavor to ensure that the careful Hatch-Waxman balance—between promoting innovation and speeding generic entry—is scrupulously maintained.

Mr. BILIRAKIS. Thank you very much, sir.

Well, all right, as I said earlier, we are going to take a break, let's say, until one o'clock. We will recess until one o'clock. Thank you.

[Whereupon, at 12:10 p.m., the subcommittee recessed, to reconvene at 1 p.m., the same day.]

Mr. BILIRAKIS. Let's get started.

Dr. Crawford, do you believe that in some instances 180 days of generic exclusivity is not warranted? For example, for some blockbuster drugs, more than 10 generic manufacturers line up to challenge the brand patent, but only the first is entitled to the 180-day exclusivity. I would ask, isn't this proof that the market is working, there's enough of an incentive?

Mr. CRAWFORD. We have looked into that. It is, obviously, a part of the law, but it hasn't been proved that it is an incentive. So we think that it is working as intended, but we don't see it particularly as an incentive.

Mr. BILIRAKIS. You don't see it as an incentive? Do you believe that in some instances that amount of exclusivity is not warranted?

Mr. CRAWFORD. There are instances where you would question it, but it has become part of the system. It is expected, and to some extent it drives the system. So I think changing that would need to be done very carefully.

Mr. BILIRAKIS. Very carefully?

Mr. CRAWFORD. Yes, sir.

Mr. BILIRAKIS. Can you describe for us the lengths that some generics go to just to be the company qualifying for that extra exclusivity?

Mr. CRAWFORD. Yes. There are instances that actually have been recorded, and I can attest to the veracity of, where people have lined up in the parking lot and spent the night, some companies in limousines, and I am told, although I haven't seen it, some in tents from time to time, waiting to be the first one in line. I don't know what all techniques are used in jockeying for first position, but it is something that is coveted, to answer your question.

Mr. BILIRAKIS. How many patent attorneys does the FDA presently employ?

Mr. CRAWFORD. We don't have any.

Mr. BILIRAKIS. You don't have any?

Mr. CRAWFORD. No, we do not.

Mr. BILIRAKIS. So you have already said it, I think, you don't have the expertise to review patent listings to determine whether a patent's claim lists the drugs, right? You just don't have the expertise?

Mr. CRAWFORD. We do not. We do not, and we also do not presume to second-guess PTO in that regard. If they issue a patent, that basically is a statement of the government. So we do not and we have not seen the need to employ patent attorneys and also a patent staff.

Mr. BILIRAKIS. Mr. Muris, in your recent report that, frankly, we thank you so very much for and we appreciate, you have recommended two narrow changes to the act, to the Hatch Waxman Act. Did the FTC consider other reforms and then reject them?

Mr. MURIS. In drafting the report, we looked at a variety of issues, but the report was premised on the idea that the original Hatch-Waxman balance made sense, and we didn't question that. What we sought to evaluate was whether the evidence showed that subsequent problems had arisen. We thought there were some problems, and, hence, we did make a few recommendations for legislation.

Mr. BILIRAKIS. All right. Just to sort of close out my portion of the questioning, I think you have heard the opening statements, and I think you can see that we all feel that reforms have to be made. The extent of the reforms, of course, is where the arguments come in, but I like to think that on a bipartisan basis, if we take into consideration fairness, if you will, certainly the intent of the act, Mr. Waxman would be helpful in that regard, and that intent, obviously, being to allow generics to get on the market quicker, but at the same time to not take away from the research and the innovations that the industry and that all of our people need so very desperately.

Having taken that into consideration, would you say that the recommendations that you have made in your report, Mr. Muris, is basically it? You have nothing further to recommend to us, knowing that we probably will address this problem, and try to address it as well as we can?

Mr. MURIS. Again, let me make clear, when I am answering these questions, I am answering them as an individual Commissioner and not on behalf of the Commission. The report is a report of the Commission. I believe it is comprehensive in the sense that it addresses the problems that we found with this empirical evaluation that we gathered.

Mr. BILIRAKIS. Okay. Dr. Crawford, anything you want to add to that?

Mr. CRAWFORD. No. I want to reiterate, as we said in the testimony, we do not oppose the idea of a single 30-month extension. That concept is something that is agreeable to us.

Mr. BILIRAKIS. Okay, but there aren't any other suggestions that you would make to this committee in terms of changes that should be made?

Mr. CRAWFORD. Not at this time. We have in our testimony several issues that we raised, but to make formal recommendations we are not prepared to do that.

Mr. BILIRAKIS. I would urge you both to make those recommendations to us on a timely basis, when you come to them, if you do.

But, Mr. Waxman, to inquire.

Mr. WAXMAN. Thank you. Thank you, Mr. Chairman.

Dr. Crawford, PhRMA has argued that provisions of S. 812 undermine protection of significant innovations in already-approved drugs by refusing to allow 30-month stays for late-filed patents. They describe as examples of such innovations new dosage forms, new dosing regimens, and changes in side effect profile.

Isn't it true that every one of these changes to a drug or its labeling would require a New Drug Application or supplement?

Mr. CRAWFORD. The way we are organized now, it would require supplements at the minimum in those cases, yes.

Mr. WAXMAN. If it were more of an innovation than the ones I have mentioned, it would require a New Drug Application, wouldn't it?

Mr. CRAWFORD. If there is a substantial change in indications and also for the drug, it is a possibility. That is rare, as you know, that we would require a total resubmission, but it is possible.

Mr. WAXMAN. Isn't it true that once there is a New Drug Application or supplement, the NDA-holder is once again free to file all patents to cover that new drug?

Mr. CRAWFORD. They are free to file, yes.

Mr. WAXMAN. So limiting 30-month stays to patents filed near the time of NDA approval wouldn't eliminate protection of any of these innovations, would it?

Mr. CRAWFORD. Not in and of themselves, no.

Mr. WAXMAN. What kinds of changes to already-approved drugs could an NDA-holder make that would constitute an innovation but wouldn't require a New Drug Application or supplement?

Mr. CRAWFORD. In terms of the usage of the drug, particularly?

Mr. WAXMAN. Any changes to an already-approved drug.

Mr. CRAWFORD. Minimal things like changing the coloration or extension of the usage language. It would be cosmetic or minimal things.

Mr. WAXMAN. You have testified that FDA has neither the expertise nor the authority to challenge patent listings by NDA-holders, and the result of this position is that NDA-holders can file patents that do not cover the approved drug and, thus, do not meet the statutory requirements for filing without challenge by the FDA, is that correct?

Mr. CRAWFORD. Yes.

Mr. WAXMAN. If the NDA-holder who has improperly filed a patent then sues a generic competitor for infringement of that patent, the NDA-holder gets an automatic 30-month stay of approval regardless of the merits of that patent, isn't that correct?

Mr. CRAWFORD. Yes.

Mr. WAXMAN. One might think that this situation demands that we provide some avenue for generic companies to challenge improper patent listings. The FTC report says that we should con-

sider providing for such an avenue. I understand that PhRMA has suggested, however, that there is no need to let a generic company challenge patent listings in court because in any case where a filed patent does not cover the approved drug FDA can bring a criminal action against an NDA-holder for filing a false statement with the government. Now this puzzles me.

Is it your position that FDA does have the expertise to determine whether a patent covers an approved drug for purposes of bringing such a criminal action but does not for purposes of challenging the filing of the patent?

Mr. CRAWFORD. Mr. Troy is going to answer that.

Mr. TROY. Congressman Waxman, what often happens is at the front end, it is not really clear whether or not what is being made is or is not a false statement. It is possible that after litigation it would become clear, but, as you well know and I think as you perceptibly pointed out in your comments, these issues are very, very, very carefully lawyered. So, basically, PhRMA companies are sophisticated enough not to sign something that is sufficiently false that we could prove beyond a reasonable doubt in court.

Mr. WAXMAN. So the probability that FDA will be bringing criminal actions against patent-filers for false statements is pretty near zero, isn't it?

Mr. TROY. I think it is quite low because, again, these things, as you say, are quite—

Mr. WAXMAN. Have you ever filed a criminal action?

Mr. TROY. No, we have not.

Mr. WAXMAN. Okay. Is it your position that generic competitors should have no remedy for improper patent-filings that could result in 30-month stays, Dr. Crawford?

Mr. TROY. Our view is that you can—proper resolution of this under Hatch-Waxman is for the courts. The courts have the expertise about patents and, as we understand the statute, the point is, if someone verifies the listing, then it is really for the courts to resolve. I think a court might have authority to require a company to delist—

Mr. WAXMAN. Do you think that there ought to be a remedy for improper patent filings that a generic competitor can challenge, so that they don't get a 30-month delay?

Mr. TROY. Not that would require FDA to get into overseeing and judging the patent listings. We don't have the expertise to do that or the authority.

Mr. WAXMAN. Mr. Chairman, will we have a second round with this?

Mr. BILIRAKIS. I don't contemplate it.

Mr. WAXMAN. May I ask—

Mr. BILIRAKIS. Let's see how we go.

Mr. WAXMAN. Okay, but at some point I would like to ask that we have the opportunity to submit questions in writing for responses in writing.

Mr. BILIRAKIS. We will definitely do that. Thank you.

Mr. DEAL, to inquire.

Mr. DEAL. We have heard reference made in your statements to the fact that there are anti-competitive agreements sometimes among brands and generics, and generics and generics. Which of

those seem to be the most frequent, the anti-competitive agreements with brands and generics or generics themselves with each other?

Mr. CRAWFORD. Brands and generics.

Mr. DEAL. What action, if any, can be taken with regard to that?

Mr. CRAWFORD. By FDA?

Mr. DEAL. Yes.

Mr. CRAWFORD. Almost nothing.

Mr. DEAL. Mr. Muris, what about with your agency?

Mr. MURIS. Under certain circumstances, those agreements can violate the antitrust laws. The Commission has brought four cases, three involving agreements between brands and generics, and one involving an agreement between a generic and another generic. We have also filed an amicus brief in another case, but it didn't involve an agreement. It involved unilateral activity.

Mr. DEAL. Do you also become involved in the generic-versus-generic cases?

Mr. MURIS. Yes.

Mr. DEAL. Have you filed any actions there?

Mr. MURIS. We have had one case there, yes.

Mr. DEAL. Okay. Explain the relationship. Do you simply ask the Justice Department to initiate action or how does the process work?

Mr. MURIS. No, we have independent authority. Most of the cases that we bring, we bring administratively as opposed to going directly to Federal court. This is what we have done in the cases that involve these branded and generic drug issues. Of the four cases that have been filed, three of them were settled with consent agreements.

Mr. DEAL. Is that an area where there needs further statutory authority to act in that area or do you think there is adequate remedy?

Mr. MURIS. We think there is adequate substantive authority in terms of the antitrust laws, although there are some very tricky issues. We do recommend that the House pass the bill that the Senate passed, which would require notification of these agreements to the FTC and the Department of Justice.

Mr. DEAL. Mr. Muris, does the FTC ever consider restricting pharmaceutical patent rights, which I understand some witnesses are going to advocate here today? Do you support any limitations on manufacturers' patent rights?

Mr. MURIS. Under the antitrust laws there are situations where patent rights may be abused. The most prevalent kind of cases, however, involve cases where there was some problem in obtaining the patent rights or in this area where patents are improperly listed in the Orange Book.

Mr. DEAL. You recommend only one 30-month stay per drug. Others, of course, take an opposite position. What is the basis for that? Is it just simply that you think that is a way to game the system with additional extensions or what?

Mr. MURIS. I think it is important to identify what we mean by a late listing. Mr. Waxman suggested that late listing was after the NDA. When we are talking about a late listing, we are talking about after the ANDA is filed. Our report identified eight instances

where that happened and where a subsequent 30-month stay was allowed.

In each instance, there are serious issues about the validity of listing the additional patents in the Orange Book. We think that, although the number is not large, the pattern is recent; the amount of commerce is very significant. We think that there is nothing in Hatch-Waxman, as it was first passed and as it was implemented, for most of its history, that indicates support for these multiple 30-month stays. Because of the problems we have seen with them, we recommend that just one 30-month stay be permissible.

Mr. DEAL. Did I understand, though, that in those cases, that maybe only one of them ran the full length of the additional stay period? Were they cut short of the full extension period?

Mr. MURIS. Yes. The additional stays ran from 4 to 40 months, but we are talking very significant amounts of money here, even on a per-month basis.

Mr. DEAL. Thank you, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman. Mr. Brown, to inquire.

Mr. BROWN. Thank you, Mr. Chairman.

Dr. Crawford—I am sorry, Mr. Muris, I would like to start with you.

It is my understanding that drugmakers that own patents are protected by preliminary injunctions and by treble damages. The 30-month stay is an extra layer of protection that has been subject to gaming, obviously, as you said in your report, and it provokes litigation, as you said in your report. Why do you, then, recommend maintaining one 30-month stay per drug?

Mr. MURIS. Again, we started with the premise that the original Hatch-Waxman balance made sense. We asked, was there any evidence that we had that indicated that there were problems? In terms of the 30-month stay, if you look at cases where there was no challenge at all, there was a period of about 25½ months before FDA approval. In terms of district court litigation, again, it took about 25½ months to obtain a district court decision of approval.

So the 30 months does not cause a problem in itself and, in fact, approximates what would happen without the court challenges. It was the multiple 30-month stays where we thought that there was significant gaming and the significant problems.

Mr. BROWN. Can that 25½ months be accelerated? Can that be shortened? If you were not recommending one 30-month stay per drug, can that 25½ months be speeded up? Can the approval time ultimately be speeded up?

Mr. MURIS. Yes. The approval occurs at the FDA, and our report does not address that possibility. We just didn't study it.

Mr. BROWN. All right, Dr. Crawford, you have opposed S. 812, as you said, and as the President had said. You have, however, the FDA has acknowledged, the President has acknowledged that there is a gaming of the patent system, that there is abuse, that there are problems here, that 32 attorneys general have said we need to do something; the FTC says we need to do something.

What is the FDA's suggestion? What do you propose to fix this problem that you, in fact—even though you have opposed S. 812, there can be other avenues—what do you propose to correct this?

Mr. CRAWFORD. Actually, what we are indicating is that this is not something that is in the usual ambit of what FDA does. We oppose the bill because of the intellectual property rights compromise and various other aspects.

This particular thing of gaming with the 30-month stays and interactions between the pioneer and the generics would normally fall within the purview of the Federal Trade Commission, and not of the FDA.

Could we ask Mr. Troy to add a bit to that?

Mr. TROY. Thank you. Let me say three things. First of all, there is game playing. There is game playing on both sides. The generics engage in a fair amount of game playing that we see, and we in the Office of Generic Drugs, in the Office of Chief Counsel, spend an enormous amount of time trying to enforce the balance of Hatch-Waxman and to apply it—it is not easy—according to its terms. We try, to the extent possible within the limits of the law, to cut down on game playing. That is point one.

Point two, I think there are two other things that I think we can do at the FDA and are looking at doing. The second is we can clarify, as the FTC suggested, we can clarify that there are certain patents that we think should not be listed in the Orange Book. We can provide more guidance on that, and we intend to do so.

The third thing that we are looking at doing, and that I have had some productive meetings with Kathleen Jaeger of GPhA about, is looking at a beefed-up declaration, meaning of the kind that is submitted by the innovator to provide additional information about the patents that they are claiming and the patents that they are listing. Those are things that are, I think, well within our administrative authority, and they are things we are actively considering and looking at doing.

Mr. BROWN. So, Dr. Crawford, can you do those things administratively and do you think correct this problem short of a statutory change?

Mr. CRAWFORD. These are the authorities we have. We actually do that as seriously as we can. There is one other aspect. There is another aspect, which is that if a patent that is filed seems to be one that is objectionable and that may be too widely drawn to fit what we normally expect, we have sent letters to the firm reminding them that their declaration that we enter into the Orange Book administratively—that is, we just put it in—but in the evaluation we have sent letters saying that you might want to reexamine this patent and what it is—

Mr. BROWN. But they still have gotten the 30-month stay?

Mr. CRAWFORD. Yes.

Mr. BROWN. Okay, so the letters really don't mean very much, except maybe they hurt the company in court? But the 30-month stay, the clock still begins to tick?

I have run out of time, Mr. Chairman, and I apologize for that.

I do want to say, though, that, first of all, you oppose this bill. Second, you say that it is not in the purview of the FDA to make suggestions on what to change statutorily. You are part of the administration. You are both Presidential appointees. I would hope the Bush Administration would come forward with some suggestions on fixing this, if they are not going to support the Brown-

Emerson bill—Ms. Emerson, a Republican, was here earlier sitting in the front row, I believe—or any of these other pieces of legislation. I would hope that the administration, through you or through HHS or in some other way, would say what they do support and do advocate.

Mr. CRAWFORD. Let me reiterate that we do favor the imposition of a single 30-month stay, not multiple—

Mr. BROWN. You support the FTC's recommendations?

Mr. CRAWFORD. Yes, we do.

Mr. BROWN. Okay, that has not been said before, has it?

Mr. DEAL [presiding]. The gentleman's time has expired. Mr. Shimkus.

Mr. WAXMAN. Mr. Chairman, I ask unanimous consent for 30 seconds to get a clarification on that.

Mr. DEAL. Without objection.

Mr. WAXMAN. If you support limiting it to one 30-month stay, isn't that what the Senate bill does?

Mr. CRAWFORD. I think it has more in it than just that.

Mr. WAXMAN. But that part you support?

Mr. CRAWFORD. We do, yes.

Mr. BROWN. To fill up the rest of the 30 seconds, I just wonder why you didn't, when you opposed S. 812 before the Senate vote, why you didn't weigh in that way saying, "We support what the FTC does, but some of these other changes in S. 812 went too far or don't go far enough." I would just put on the record that I would hope that you would take that position.

Mr. CRAWFORD. Thank you.

Mr. DEAL. Mr. Shimkus.

Mr. SHIMKUS. Thank you, Mr. Chairman.

I am going to throw up a timeline and a chart. I am actually going to do it for both panels and probably will not ask too many questions of this panel on this.

As many of the folks here who are observing this know, I don't serve on this subcommittee. I am honored that you let me be in this process.

But what I am going to ask both panels is, the first question is: Based upon your involvement, is this a relatively accurate depiction of what goes on? I know the FDA, you are just checking whether the drug is safe for human consumption. We have you here at the New Drug Application, the New Drug Application approved, and that would be you. That is when it gets placed into the Orange Book, is that correct?

Mr. CRAWFORD. Yes.

Mr. SHIMKUS. Do you actually have, it is actually a big orange book?

Mr. CRAWFORD. Actually, it is both electronic and published with an orange cover.

Mr. SHIMKUS. Okay, good. I was hoping that it was just not a three-ring binder that we are sliding papers in.

Then you are also, FDA is also involved at the Abbreviated New Drug Application, is that correct?

Mr. CRAWFORD. That is correct.

Mr. SHIMKUS. Now, Mr. Muris, the patent infringement suit comes by the generic drug companies saying a lot of things. They

are saying this shouldn't be patent-protected and we should have access to sell this drug now, is that correct?

Mr. MURIS. Yes. There is what is called a paragraph IV certification, where the generic applicant is claiming either the patent is invalid or the generic does not infringe.

Mr. SHIMKUS. So if that occurs in that timeline and then, of course, the patent infringement suit is filed, that is the whole debate of the 30-month stay, is that correct? I mean, when that is filed, you get the 30-month stay?

Mr. MURIS. Yes, unless there is a court decision earlier.

Mr. SHIMKUS. Okay. Now that is coming before the end of the original patent term for the most part?

Mr. MURIS. Yes. Obviously, this whole issue and our whole study was directed to the issue of prior to patent expiration.

Mr. SHIMKUS. Have there been cases where, on the whole debate we just had on multiple 30-month stays, have there been multiple 30-month stays that still fall short of the original patent term of 20 years?

Mr. MURIS. Yes. Yes.

Mr. SHIMKUS. Do we know how many?

Mr. MURIS. There must be. Of the eight cases that we have, the whole issue of paragraph IV becomes irrelevant once the stay expires. Thus this area involves through the life of the patent. If you are talking about beyond the life of the patent, you could file what is called a paragraph III certification.

Mr. SHIMKUS. Okay. If—

Mr. MURIS. I'm sorry, go ahead.

Mr. SHIMKUS. No, that is all right. If, the way I have talked to, again, many folks here, and as I have been trying to struggle with this understanding chemical compounds, if you had a basic chemical compound and it got a patent application and it got filed and it got approved, and you said that formula, the patent term for that formula is 20 years, if we would craft legislation that just said, at the end of the patent life, 20 years for that chemical compound, it is over, wouldn't that solve a lot of problems and a lot of bureaucracy and a lot of court cases?

Mr. MURIS. I think part of the reason underlying Hatch-Waxman is that there are a variety of patents and a variety of complexities. Certainly allowing the generics to cut through a lot of the drug approval process, which Hatch-Waxman allowed, in fact, dramatically increased generic entry.

Mr. SHIMKUS. That is the term "bioequivalency"? Is that what we are referring to, the ability that generics, because they in essence—I don't know the proper terminology—get the information, the research that has been done, through the pharmaceutical research and development, they can say, "Okay, that's been done. We don't have to do that. Then we can jump up here."?

But the question is still the same. Then it marries up, as we tinker with reformulation. And I am going to ask this to the next panel; I am going to use the same chart. If a patent is filed and approved for a chemical compound and patent law says 20 years, except for pediatric exclusivity, which we through public policy have said is a good thing to extend, why not just say it is done?

Why not prohibit the immediate review and the post-review and these 30-month stays and just go to the end of the patent?

Mr. WAXMAN. Would the gentleman yield to me?

Mr. SHIMKUS. Yes, I would.

Mr. WAXMAN. The idea of the law was that there is time spent at FDA to get a drug approved. A lot of the companies felt that, since they can't market their product until FDA approves it, that they should have restored to them part of the time at FDA. We felt that was a wise public policy measure to take because we wanted to give every encouragement for the investment.

But we do want in that law the balance. At the end of the patent period and the patent restorations we want competition. We want generics to be approved and then to be able to go on the market.

What we have seen is something we never envisioned when the law was adopted. The 30-month delay is different than what happens ordinarily in patents. Ordinarily in patents if a competitor goes out and sells a product, if you feel he has violated your patent, you sue him and you get treble damages. You can't stop him, often-times you can't stop him from infringing, but you can get tremendous damages.

In 1984, a lot of the brand-name companies said to us, "We are not sure that if we sue for treble damages these generic companies will be viable enough to pay us the damages. So we would like to have the assurance that, if there is an infringement of the patent, we will have a stop of any competition for 30 months."

What has happened is that these generic companies are viable. They could recover damages. I don't think any of these patent infringement lawsuits have ever succeeded. But the consequence of that 30-month stay has meant that in recent years, not in the beginning but in recent years, they can just file a frivolous lawsuit and then stop a generic from going on the market. Then they can come in with another frivolous patent and follow it with a lawsuit and get even a further extension—

Mr. SHIMKUS. If I can reclaim my time, though, going back to the chart, if there are cases where there are duplicate 30-month stays, that stills fall short of the original patent term?

Mr. WAXMAN. Well, if the gentleman would yield, the time is restored, so that the original patent term is in effect extended to these under that time.

Mr. SHIMKUS. Yes, this is really for infantrymen, a simpleton, this is—I am trying to get a handle on this, and I appreciate my colleague's patience. I will ask this again in the next panel.

I yield back my time.

Mr. DEAL. Mr. Pallone.

Mr. PALLONE. Thank you.

I have to say, Dr. Crawford, I am very frustrated by the testimony today because I don't think you are really being helpful in terms of telling us what needs to be done here. Let me just outline.

I mean, I see this FTC report as being extremely helpful and basically saying that there is abuse of the system with the 30-day stays, with the Orange Book listings. Then Mr. Troy says, "Well, there's gaming on both sides of the aisle or both sides, generic and"—not the aisle, I guess that is wrong—you know generics and brand-name, almost like you are trivializing the problem that we

have been highlighting here with the Orange Book listings and the 30-day stays.

Then, Dr. Crawford, you say that the FDA can't really address the abuses outlined in the FTC report about the Orange Book listings. Then, with Mr. Waxman, you said that the agency doesn't have the resources or expertise to review patents, and even with additional funding, you are not going to be able to obtain the resources. Then you come and tell us, "Well, we are not in favor of passing S. 812 because it is going to stifle innovation."

I mean you are either an expert or you are not. I mean you are either going to tell us that there is something to be done here to correct these abuses that the FTC report has outlined on both sides—I mean, S. 812 addresses the generic abuses as well as the brand-name abuses, if you will. But, you know, it can't be both ways. It seems to me you are almost like saying two things at the same time.

You either have the expertise to tell us that S. 812 is not a good idea because it is going to stifle innovation and then you can't come back and tell us, "Well, we don't have the expertise to deal with addressing the abuses." Why do you feel that S. 812 is going to stifle innovation? It seems to me that it doesn't do anything that is damaging to the patent system. I don't understand that statement at all, and I don't understand how you are saying both of these things at the same time.

Mr. CRAWFORD. I am going to ask Mr. Troy to follow up, but what I had reference to is that FDA basically does not have expertise in patent law.

Mr. PALLONE. Right, but then you tell us we shouldn't pass S. 812.

Mr. CRAWFORD. Yes.

Mr. PALLONE. So why, if you don't have the expertise, why are you telling us that?

Mr. CRAWFORD. I can give you two things. One is the original statement that the administration put out, which is very brief. That is, we support steps to encourage fair competition and appropriate use of generic drugs and recognize that some adjustments to current law would improve the fair entry of generic substitutes into the market and prevent future abuses of the patent law.

Mr. PALLONE. What do you want us to do? You say that S. 812 is no good. Why is it—

Mr. CRAWFORD. I have already said that one thing that we do not oppose is a system where there is only one 30-month extension. Presently, there can be multiple 30-month extensions.

Mr. PALLONE. But tell us why you think that S. 812 is going to stifle innovation. Why is there a problem? It clearly addresses the problems on both sides that the FTC report brings up. So why is it a problem? Why isn't it a good thing? Because you say you don't have the power to address these abuses.

Mr. CRAWFORD. Right.

Mr. PALLONE. We are going to fix it by passing the Senate bill, but then you tell us it is not a good idea and you don't have the expertise, but you are telling us anyway.

Mr. CRAWFORD. I am going to ask Mr. Troy to make some specific references to our testimony, and then I will follow up with a more—

Mr. PALLONE. But I want an answer to my question about why we shouldn't pass S. 812.

Mr. CRAWFORD. That is what he is going to give you.

Mr. PALLONE. Okay.

Mr. TROY. The problem with S. 812, Congressman Pallone, is not that it would restrict multiple 30-month stays. There are a host of other things that are unfortunate add-ons to S. 812, and I will give you two specific ones.

Mr. PALLONE. So you don't have a problem with the aspect, with the 30-day stay?

Mr. TROY. The administration never said it had a problem with that.

Mr. PALLONE. Okay, keep going.

Mr. TROY. One is that it would allow any generic manufacturer to sue sponsors to correct or delete patent listings, and we believe that that provision would encourage lawsuits.

The second, and much more important, problem is that, if you fail to file certain things within timeframes, it would permanently bar patent-holders from bringing suits for patent infringement. It is one thing to target a bill that focuses on the later-listed patents and the 30-month stay issue, the multiple 30-month stay issue.

What S. 812 does is it goes beyond that and seems to impose barriers and seems to attack the so-called good patents, the upfront patents, the \$800 million patents—

Mr. PALLONE. I am running out of time. Aren't those a little specious by comparison to the good that is done in addressing the FTC problems that have been raised?

Mr. TROY. The FTC does not call for any of those additional things that are in S. 812.

Mr. PALLONE. No, I understand, but I mean the things you are mentioning pale by comparison to the good that would be achieved.

Mr. TROY. With all due respect, Congressman Pallone, it seems to me that, if you end up forfeiting patent rights, not the successive 30-month stay but forfeiting the patents, and these are the patents that go to the NDA, not the later-listed patents, that that could have very dramatic consequences for innovation. That is the problem.

Mr. WAXMAN. Would the gentleman yield?

Mr. PALLONE. Yes.

Mr. DEAL. The gentleman's time has expired.

Mr. WAXMAN. I ask unanimous consent the gentleman be given 1 additional—

Mr. DEAL. Let's follow regular order.

Mr. WAXMAN. I asked unanimous consent. If somebody objects—

Mr. DEAL. Are there objections?

[No response.]

All right.

Mr. PALLONE. I yield to the gentleman.

Mr. WAXMAN. Just to clarify the point, Mr. Troy, you are saying you don't want the generics to be able to do anything to delist a

patent they don't think is valid because you think it is going to encourage lawsuits. But the whole idea of the 30-month stay, based on a lawsuit by the brand-name companies, encourages frivolous lawsuits on their part.

In my point of view, as the original author of this bill, I don't even think we ought to have one 30-month stay. The reason for it originally doesn't exist today. But if you are talking about encouraging lawsuits, if you can't judge whether a patent is valid or not, why not let a generic company file a lawsuit to delist it and let the courts decide, because you don't have the capability at FDA to decide this issue?

Either way, it is going to be a court deciding it. Either way, you think the lawsuits are not going to be meritorious; let a court decide it.

Mr. PALLONE. Before the time runs out, could I ask you to send us something, with the chairman's indulgence, to send us a followup about those issues that you mentioned with regard to S. 812? I would really like to see you provide more details about those comments that you made, if you could.

Mr. TROY. I think what I am saying is in the statement of the administration policy—

Mr. PALLONE. Okay.

Mr. TROY. [continuing] and we would be happy to send you that.

Mr. PALLONE. Okay.

Mr. TROY. It is one thing, Congressman Waxman, if I may, for the consequence to be the loss of a successive or even first 30-month stay. That would be one thing. But if they don't list things properly, they lose the opportunity to get even a first 30-month stay. I am not saying that the administration endorses that, but that is one consequence or remedy.

But the remedy that S. 812 imposes would be the loss not just of the 30-month stay, but of the ability to enforce the underlying patent. The intellectual property rights themselves would be at stake and would be at issue. That is the problem.

Mr. WAXMAN. I don't see that. I don't see it. I know my time has expired, but I think you are offbase on that. I think you are wrong.

Mr. DEAL. Mr. Burr.

Mr. BURR. I thank the Chair.

I want to take this opportunity, Dr. Crawford, to say welcome, as well as to our witness from the FTC.

It is not too tough to believe that we would have difficulty trying to interpret what Hatch-Waxman did because, in fact, it was a political document. It was as much a political document as it was a policy statement. At the end of a day in a room there was give and take to try to meet the needs and define the balance that, Dr. Crawford, you have mentioned as an agency you try to maintain.

That is very difficult to maintain over time because times have changed. There are more generic manufacturers at the gates ready to produce products to fill the need in the pipeline, and there are clearly more New Drug Applications this year than there were last year that do seek some type of patent protection.

I guess my first question to you is, if we eliminated patent protection for the pharmaceutical or biologics or medical device industry, what would happen?

Mr. CRAWFORD. Well, what would happen is what has happened in many other countries. That is that pharmaceutical research and development would decline.

We have talked earlier in this hearing about prices and price schedules, and how drugs are cheaper in certain other countries. Those are, for the most part, countries that do not develop drugs. The world depends on the United States, the viability of the United States pharmaceutical research and development establishment.

One of the reasons that it is able to do what it does to regularly supply the world not only with effective drugs of longstanding, but new, breakthrough drugs that really mean something to individual disease sufferers is because of the equanimity that has been imposed by bills such as Hatch-Waxman in its original form and also because of FDA's steady drive to do a more effective and efficient job of approving these drugs and getting them on the market.

Mr. BURR. In fact, in doing that, the quality of life for patients across this country has been improved, and in many cases we have shifted what was before limited options, some surgical, some inpatient, and we have defrayed that cost. Even though pharmaceutical cost has increased, the options that we have supplied to patients are that much more. That is beneficial, and I think most in this country agree.

The debate today is on a very small piece of the pie. We would all love to see more generics to the marketplace faster, but I think we all agree not until the patent life is over.

Now both of our witnesses today have talked about some people who want to game the system. I want to go to the FTC study that was released in June. I think in that study it suggested that since 1992, if my numbers are correct, there were 8,000 Abbreviated NDAs filed. In fact, in that same period there were 104 NDAs and ANDAs with paragraph (IV) certifications, meaning there were 8,000 generics that wanted to come to the marketplace.

There are 104 that fall into this category that we are here discussing today. Twenty-nine of the NDA-holders didn't question it. So that left 75 that NDA-holders sued on. Of those 75, 53 of the NDAs have had resolution, two where the patent expiration expired before the litigation. Twenty cases were settled. Twenty-two generic applications were won. Eight brand-name companies won. The NDA was withdrawn before litigation resolved in one.

On the other side of the coin, there were 22 where the 30-month stay and/or additional-month stays went into effect. Fifteen are in the initial 30-month stay period. Seven—seven—are in additional 30-month stay periods because the initial 30-month stay has expired, less than one-tenth of 1 percent of the applications that have been filed.

Mr. Muris, am I correct with your chart?

Mr. MURIS. Yes, but I think the relevant universe is much smaller. I think the relevant universe that we studied, in fact, were the 104 brand-name drug products since 1992. Of that universe, we found 14 instances where there was an agreement with the potential to park the 180 days, which could be a problem, and we found eight cases of these late-listed patents that certainly appear to be problems.

Thus, I certainly agree with the implication that in the overwhelming majority of instances there aren't problems, but I think the relevant denominator is somewhat smaller.

Mr. BURR. My time has run out, but I would say that on a number of those that you just gave a number to, Dr. Crawford's and the FDA's intent to try to look at those patents and I guess evaluate whether they were substantial enough to contribute to the health of the individual and to the efficacy of the product, an enhancement, a true enhancement other than cosmetic, would, in fact, solve the majority of the numbers you just talked about.

I believe the hope of every member of this committee is to develop a way for generics to come in a quicker way, in a more abundant way, to where there's competition throughout the marketplace. I thank both of you for helping us get there.

I yield back.

Mr. DEAL. Dr. Norwood.

Mr. NORWOOD. Thank you very much, Mr. Chairman.

Dr. Crawford, nice to see you again.

Mr. CRAWFORD. Good to see you, sir.

Mr. NORWOOD. Thank you for being here with us.

Mr. CRAWFORD. Thank you.

Mr. NORWOOD. Over the last 20 years, we have gone from 80 percent brand and 20 percent generic to 50 percent generic, which is probably a good thing. Tell me just your feelings about what would happen to those numbers should we pass the Senate bill and it becomes law.

Mr. CRAWFORD. Well, I think we would lose ground. It is not possible to say what the percentage change would be. One is tempted to say we might go back the way we were before Hatch-Waxman, but we don't have enough evidence to make a statement like that. But it is my opinion that we would lose ground.

Mr. NORWOOD. When you say, "Go back like it was before we had Hatch-Waxman," does that mean we would go back and we would have 20 percent brand and 80 percent generic?

Mr. CRAWFORD. No. No, it doesn't mean that. I can't predict that. But I think that what would happen is, if there is a compromise of intellectual property rights such as Mr. Troy outlined, what happens in cases like that is a company has to determine whether or not they are going to pursue the approval of a product or a category of products or whether or not they would keep producing what are called "me-too" products, that is, those that are already on market in slightly different forms, as you well know.

So I think there would be a compromise of the robust R&D environment that we have seen over the last few years, a great deal of which has been due to Hatch-Waxman.

Mr. NORWOOD. Well, I get the feeling that those who would like the Senate bill just as it is like that idea because they think that we will get a great deal more generics to the market. I mean, that is what I sense out of this conversation that I hear for people who are for it.

I keep wondering how the patient would fare in that, if in fact this bill allowed the market to change to the point where 75 percent of the drugs—and, clearly, that has to relate to R&D is what I mean by the patient and innovative new drugs. Can't any of us

even speculate a little bit? Might not that bill as it is almost reverse what has happened in Hatch-Waxman over the 20 years?

Mr. CRAWFORD. I would say one thing that it would do, in my opinion, as you know, for every generic drug and every application or certification under Hatch-Waxman there is a referenced innovator drug. There is a pioneer drug that is on the market and that was produced by this system that I described a few minutes ago.

Eventually, if there is a tamping back of the R&D enterprise in this country, and I don't see any other country able to make up for that slack, there won't be as many generic drugs because there will be nothing to reference. Any viability in the generic drug industry would largely be a representation of imitations of products that we already have on the market.

So, in order to have a viable generic drug industry and one that really does good for the sick people of this country, you need a viable R&D enterprise.

Mr. NORWOOD. So might not we be where we need to be without passing this bill?

Mr. CRAWFORD. Without passing——

Mr. NORWOOD. Passing the Senate version.

Mr. CRAWFORD. [continuing] the Senate bill?

Mr. NORWOOD. Yes. Might not we be taking some risk in passing that bill?

Mr. CRAWFORD. Yes.

Mr. NORWOOD. Mr. Troy, Mr. Waxman disagreed with you on S. 812 and patent infringement and changing the patent laws. Were you giving a legal opinion?

Mr. TROY. Not really. I was reading from page 10 of S. 812 which says, "No claim for patent infringement," that says, "An owner of a patent with respect to which a holder of an application under subsection (b) of 505, if they fail to file information on or before a date required, shall be barred from bringing a civil action for infringement of the patent against a person that."

So the point is, if you fail to file the requisite information or a court determines that you didn't file the requisite information, then you lose the ability to have, to quote the title, "No claim for patent infringement." Later, on pages 15 to 16, it says, "Failure to bring an infringement action," and "you are barred from bringing a civil action for infringement of the patent in connection with the development and manufacture, use, offer to sell."

The point is it is not just about eliminating one 30-month stay per NDA, as the FTC recommends. What S. 812 does is it goes far beyond that, and it would compromise intellectual property rights in a manner that is damaging, as you suggest and as you propose and as you are talking about.

Mr. NORWOOD. Mr. Chairman, I see the red light. I am sure not through, but I will thank you for the time.

Mr. DEAL. Mr. Stupak.

Mr. STUPAK. Thank you, Mr. Chairman.

Mr. Muris, what can you tell me about these late-filed patents? We have heard that some of them don't actually cover the approved drug. What about the late-filed patents that do appear to cover the approved drug? PhRMA would argue that they cover important in-

novations that must be protected, but in the FTC's experience how often do they represent important innovations?

Mr. MURIS. Our complaint and problem with these eight late-listed patents on eight drug products deals with the listability. We think that patents on all eight drug products could be the subject of non-frivolous challenges, and in four of them, courts have ruled that the patent was either invalid or not infringed. In a fifth, we have a consent agreement where we have successfully challenged a late-listed patent.

We therefore think there are serious problems with late-listed patents. Again, by late-listed, I mean our definition, which is different than S. 812's definition. Our definition would be after the ANDA.

Mr. STUPAK. Sure. Well, the possibility that significant delays do occur, and I think we have seen somewhere from after the 30 months it was 4 months to as many as 40 months—

Mr. MURIS. Yes.

Mr. STUPAK. [continuing] before the issue is resolved, so you have a lot of delay. Based upon either it is late-listed or improperly filed patents, it would suggest at least that we need some mechanism to challenge these patent listings. Is there currently a viable method for generics to challenge questionable patent listings? Do you agree or disagree that there should be some mechanism involved?

Mr. MURIS. There is not. In fact, the courts have held there is not. But we recommended a narrower right of action than S. 812. We recommended that the generic be allowed to file a counterclaim challenging the listing. We think, if there wasn't a suit against the generic in the first place, there wouldn't be a problem. So we think the counterclaim would take care of the issue.

Mr. STUPAK. Okay. Dr. Crawford, if I may, along these lines of questioning then, who is responsible for assuring that patents are properly listed in the Orange Book?

Mr. CRAWFORD. We enter in the Orange Book on an annual basis with an updating of each approximately every 30 days, but FDA does that ministerially. When the patents are submitted to FDA, we simply list them. We make no judgment about them.

Mr. STUPAK. Well, don't you think there should be some judgments made before they are listed in the Orange Book, so we don't have these problems and delays, especially with generics?

Mr. CRAWFORD. The problem is that the PTO has granted the patent, and it has never been, ever since the advent of the Hatch-Waxman, it has never been the province of FDA to challenge that. Another agency of the government expert in patents and trademarks has basically issued a patent, and we have not done that.

Mr. STUPAK. Sure, but since the Waxman-Hatch Act has been involved, this has been an ongoing problem. Since 1998, it has only increased, hasn't it?

Mr. CRAWFORD. Since 1998—

Mr. TROY. Well, if I may, Congressman?

Mr. STUPAK. Sure.

Mr. TROY. In fact, the problem is, if you end up allowing a lawsuit against the FDA, because that is what would happen if you got us into the judgment of listing and delisting patents on a discretionary basis, you would end up having a lawsuit anyway. So I

thought that the wisdom of Hatch-Waxman was to say, "Look, the courts really are the province. They are experts in assessing the validity of patents once they have been granted by the Patent and Trademark Office."

So the statute says, upon the submission of patent information under this subsection, the Secretary "shall" publish it. Courts, including the Fourth Circuit Court of Appeals have held that that is an administrative burden on us, and we have no discretion.

In addition to the—

Mr. STUPAK. You have no discretion, so you are claiming. But, obviously, you have recognized a problem here. So my question is: Has the FDA sent up to Congress—because they say, "We wash our hands of it. Congress has to resolve this." Have you sent up any language or anything to Congress saying, "Here's how we would suggest you fix this, so we don't have these loopholes and delays in getting generics to the market."?

Mr. TROY. Well, to the extent that any such language would get us in the business of reviewing patent listing, we are not actually interested in sending such language because it gets us into a business that we don't think we can do. Again, I don't think it would fix the problem because it would just engender litigation against us. We've got enough.

We have promised, I have talked about here, a number of things that we think we can do, like beefing up the declaration and like clarifying which patents can and cannot be listed in the Orange Book.

Mr. STUPAK. But even if you did all that, how do you intend to enforce the regulations, and then what goes into the Orange Book?

Mr. TROY. Again, I think a beefed-up declaration, along the line that GPhA has proposed, would cut down, that plus clarification about what patents we think can and cannot be listed in the Orange Book would do a lot to cut down on listings that are improper. That is point one.

Point two, again, we have said we do not oppose the idea of a single 30-month stay per ANDA. One of the reasons why people are so concerned about listings is because of the effect on the multiple and successive 30-month stays. If that problem were to go away, then you don't really have to spend a lot of time, it seems to me, on the listabilities and the listings issues.

Mr. STUPAK. But what I am hearing is, "if this problem goes away"; that is a lot of "what ifs." The problem hasn't gone away. That is why, graciously to the chairman, we are having a hearing on this today.

Actually, if you take a look at the brief that you filed in the Apotex case—is that the way you say it?

Mr. TROY. Yes, yes.

Mr. STUPAK. You took the position there that there is a sufficient sanction to penalize companies who do not list patents in the Orange Book. On the other hand, the agency has opined that there is no penalty within the Food, Drug and Cosmetic Act for over-listing patents in the Orange Book.

So which is it? You've got sanctions or you don't have any sanctions? What is the appropriate enforcement mechanism, is what I am trying to get at?

Mr. TROY. As we have said, I think the appropriate enforcement mechanism is for the courts to assess the validity of the patents, as in the context of that challenge, we have neither the resources, the expertise, nor the authority to be reviewing the substance of the listings. Again, it wouldn't really help because we would end up in court with us being sued instead of the parties suing one another.

Mr. DEAL. The gentleman's time has expired. Mr. Buyer.

Mr. BUYER. To the FDA, on page 15 of your testimony, you lay out four specific positions of the administration: harm to innovation and investments, will encourage litigation, reduce patent protections for drug developers. The Senate bill will also delay availability of generic drugs, reduce price competition. Those are four biggies.

If the Senate bill were to be adopted as written by the House, based on these four positions, is this a piece of legislation that the President would veto?

Mr. CRAWFORD. I cannot speak for the President.

Mr. BUYER. All right, let me repose the question.

Mr. CRAWFORD. Yes.

Mr. BUYER. Would you submit a recommendation to the President to veto this bill, based on these four criteria?

Mr. CRAWFORD. That would be done north of me.

Mr. BUYER. Now let me rephrase. Let me rephrase. You have a tremendous responsibility here.

Mr. CRAWFORD. Yes.

Mr. BUYER. So what is your personal opinion in recommendation to the President, based on these four criteria, the administration's position?

Mr. CRAWFORD. I would hope this bill would not become law.

Mr. BUYER. That would be your personal opinion?

Mr. CRAWFORD. Right.

Mr. BUYER. To the FTC, in reviewing Senate bill 812, I notice that the bill would bar innovators from suing to enforce patents not listed in the Orange Book by certain deadlines. Is that something that the FTC recommended in its report?

Mr. MURIS. No, it was not.

Mr. BUYER. I also see, under Senate bill 812, an innovator would have to sue within 45 days' notice in order to enforce its patent or lose all future rights to sue. Is that something that was recommended in the FTC report?

Mr. MURIS. No.

Mr. BUYER. I also notice that it would create rolling eligibility for an award of 180 days' exclusivity. Is that something that the FTC recommended in its report?

Mr. MURIS. No. There are, as you are going through here, there are several differences and inconsistencies between S. 812 and the FTC report.

Mr. BUYER. What about the limiting 30-month stays for certain kinds of patents? Was that in the FTC report?

Mr. MURIS. I am not sure what you are driving at.

Mr. BUYER. I will get there. What about creating a private right of action for delaying patents? Was that a recommendation from the FTC report?

Mr. MURIS. No.

Mr. BUYER. The FTC report was over a year in the making and represents the agency's views on how Hatch-Waxman should be amended to facilitate generic entry while protecting incentives to innovate, is that correct?

Mr. MURIS. Yes, I believe that it was clearly a balance.

Mr. BUYER. So, as I go through and hit the highlights here, none of these things that are in Senate 812 were recommended by the FTC. Your agency examined this a year in the making and now has testified that you attempted to strike a balance. So your testimony here today would be that Senate 812 does not strike the proper balance for this country?

Mr. MURIS. Let me make clear what the Commission said and what I am—

Mr. BUYER. No. Will you answer that question yes or no?

Mr. MURIS. I can't answer it yes or no. So I won't say anything.

Mr. BUYER. So Senate—all right, let me ask this.

Mr. MURIS. Would you like an honest answer or would you like—

Mr. BUYER. No, I am going to ask this.

Mr. MURIS. Okay, fine.

Mr. BUYER. I don't want you to waffle and that is what you are about to do.

Mr. MURIS. No, I am not about to waffle.

Mr. BUYER. It is a very simple question.

Mr. MURIS. Happy, I am not about to waffle.

Mr. BUYER. Then give me your answer.

Mr. MURIS. All right, thank you. The Commission—I am just trying, and I apologize for getting a little hot there, I am just trying to distinguish between the Commission—

Mr. BUYER. I asked you a very simple yes-or-no question, sir.

Mr. MURIS. I am trying to distinguish between the Commission, which is five people, and me, which is one Commissioner. That is all I am trying to do. If you will let me do it, I will do it.

Mr. BUYER. Do it.

Mr. MURIS. All right. The Commission issued a report which it thought addressed the problems. There are some inconsistencies with S. 812, and there are some differences.

Now when the Commission was doing the report, we didn't have before us S. 812. My personal opinion is that there are several parts of S. 812 that I would not favor. Indeed, I would favor what is in the Commission's report as to what is in S. 812. But, again, the full Commission itself has not taken a position on S. 812.

Mr. DEAL. Mr. Pickering.

Mr. PICKERING. Mr. Muris, to follow up on that line of questioning, what are the provisions in H.R. 5311 or the Senate bill where you do agree?

Mr. MURIS. Well—

Mr. PICKERING. Not where you disagree, but where you would agree?

Mr. MURIS. I certainly agree that we should have one 30-month stay.

Mr. PICKERING. There is some disagreement on whether it starts with the NDA or the ANDA.

Mr. MURIS. Yes. Yes.

Mr. PICKERING. What are the consequences of those two?

Mr. MURIS. That is an important question, and I am not positive of the consequences. Let me explain why.

If you look at what we found, and this is not in our report because, again, we did not have S. 812 before us; we had these late-listed patents on eight drug products. That means late-listed after the ANDA was filed. But if you look at the 75 cases that we had where the NDA-holder sued the first ANDA filer, 17 of those would fit in the period between the NDA approval plus 30 days, which is the S. 812 standard, and the filing of the ANDA. In all of those cases I believe the patent was sought before the NDA approval plus 30 days.

Most of these issues deal with formulation patents. Unless the branded companies could, under the S. 812 standard, have the patents approved more quickly, then the S. 812 standard would result in a significant difference with what we have proposed.

What I don't know, and what you could ask the next panel, is what extent does that difference make. We found there are actually 23, and not 17. Six of the 23 were, in fact, issued before the NDA was approved. But they just didn't get around to filing them in the Orange Book. That is one of the differences.

I realize this is very complex, but this could be a very significant difference between S. 812 and the recommendation that we made.

Mr. PICKERING. Would you oppose the S. 812 standard of NDA versus ANDA when the clock starts on a 30-month stay?

Mr. MURIS. I prefer our standard, but what I am saying is, I could be convinced—

Mr. PICKERING. Yes, you are not as adamant on that issue as you may be on some of the other issues?

Mr. MURIS. Yes, because I don't know to what—

Mr. PICKERING. That might be an area of compromise?

Mr. MURIS. What I would want to know, the reason is I am uncertain factually about the significance of this group in the middle, the 17 that we had. If, in fact, they could not accelerate patent approval, then I think that S. 812 would be working a major difference.

Mr. PICKERING. But the objective would be to stop the gaming and to have the generic available on time, when the—

Mr. MURIS. Right, but what I am saying is, these 17 cases did not involve, as far as we could tell, the kind of gaming that the later-filed patents on the eight drug products did. So I am saying, again, I would want to know factually from people in the industry and talk to people at the FDA about what the significance would be of adopting the S. 812 standard.

Mr. PICKERING. But would it be fair to say that the FTC is open on that issue?

Mr. MURIS. Well, again, when I am answering these questions, I am speaking only for myself.

Mr. PICKERING. You just want more information? You could be convinced by the industry if you see no adverse consequence?

Mr. MURIS. Sure, if, in fact, the 17, for a variety of reasons, could have qualified under the S. 812 standard, that would be very important to know.

Mr. PICKERING. Okay, Mr. Chairman, if I could have just one other line of questioning?

On the 180-day exclusivity, does the FTC recommendation conform to S. 812 and the Thune legislation in the House? Does it differ? Do you have a significant issue with the proposed legislation as it addresses exclusivity?

Mr. MURIS. Yes. Again, the Commission did not address S. 812, but the report does not suggest that the 180 days should roll. Again, not speaking for the Commission because the Commission hasn't talked about this—I think that rolling can be a process for gaming.

We have seen in some of our cases, when you treat the 180 days as a currency that can be traded——

Mr. PICKERING. Should we just do away with the 180-day exclusivity?

Mr. MURIS. We approached this as accepting the original Hatch-Waxman balance and accepting the 180 days as a fact. We saw nothing that we looked at that told us that there was a major problem with the 180 days in and of itself. Thus, I personally would not recommend eliminating the 180 days.

Mr. PICKERING. Could you modify it to have 180 days but you must go to market within that time?

Mr. MURIS. We have made three recommendations for clarifying when the 180 days begins to run. We think those recommendations, if they were accepted, would go a considerable way to eliminating problems.

Mr. PICKERING. Let me summarize real quickly where I think we might be. So FTC would make a compromise on NDA versus ANDA and on the 180-day exclusivity. On the rights to litigate, that is a more complicated and difficult task of reaching agreement. Would that be a fair summary of where we are?

Mr. MURIS. Let me summarize very quickly. There are several provisions of S. 812 that are inconsistent or different. Again, not speaking for the Commission—I personally would prefer to stick with what is in the Commission's report and not what is in S. 812. But, the Commission, not just me, does believe there should be legislation.

Mr. PICKERING. Thank you.

Mr. DEAL. The gentleman's time has expired. Mr. Wynn.

Mr. WYNN. No questions. I yield.

Mr. WAXMAN. I thank you for yielding. I thought Mr. Pickering's line of questioning was very helpful.

Let's go back to the 180 days. The 180 days was put in there to give an incentive for a generic to step to the plate and challenge it, but we never thought the 180-day right to the generic to block another generic was going to be used as a way for a collusive agreement to stop any generics. So aren't we trying to deal with that problem, not to eliminate the 180 days but make sure that the 180-day does not become a barrier for any generic to get on the market?

Mr. MURIS. I agree with that, and that is the issue to which the Commission's report was addressed. I am afraid that S. 812, by allowing it to roll, could result in analogous sorts of games where, in fact, 180 days is extended and does become a barrier.

Mr. WAXMAN. That is a fair issue to look at.

Now on the question on the 30-month stay, the FTC recommended that if the patent-holder/approved drug manufacturer wants to stop a generic from competing, they can simply claim another patent. Then if the generic manufacturer wants to come in and compete, they can file a lawsuit, and that automatically stops that generic from competing for 30 months, which is a substantial period of time.

The FTC has suggested that the generic manufacturer ought to be able to go to court in a counterclaim and say that the listing of the patent was not legitimate. Now my question to you is, what good does it do for the manufacturer of a generic company to make a counterclaim if they still get that 30-month period where they still can't compete, even if it was completely frivolous?

Mr. MURIS. I understand. Again, we support eliminating the multiple 30-month stays. There is an additional issue here which some of you have raised, which is there is no way to challenge the validity of a listing.

Mr. WAXMAN. Right.

Mr. MURIS. We think, rather than a new private right of action, a counterclaim would be adequate to the task.

Mr. WAXMAN. But a counterclaim doesn't solve the problem of the 30-month stay that would go into effect. So by the time they have their issue resolved, and it turns out that it was a frivolous patent, they have still lost 30 months.

Mr. MURIS. I agree, but, again, you need to couple our recommendations. You've got to consider our recommendations as a group.

We would eliminate the multiple 30-month stays. We think the problem—

Mr. WAXMAN. I am talking about if we have one 30-month stay.

Mr. MURIS. Okay, we found very few examples of the same sorts of challengeable patents in the original group as compared to the late-listed group.

The second point is, the 30 months turns out to be a fairly good approximation of what happens in reality, how long it takes—

Mr. WAXMAN. A lot of the generic companies dispute that. Some of them say they are getting approved faster, and the public ought to have the ability to have a generic, lower-priced drug whenever it is appropriate. We shouldn't have an artificial 30-month stay if it is not based on a legitimate application of the law.

Mr. MURIS. But the reality is—let me make two last points. One, obviously, the counterclaim would terminate, if you went with the counterclaim, it would terminate the 30-month stay, just as now, if you win, it terminates a 30-month—

Mr. WAXMAN. That is only if you win.

Mr. MURIS. Sure.

Mr. WAXMAN. But the 30-month stay was supposed to stop a generic from competing 30 months or before the court acts, but there is no reason to want to get into court faster. Isn't the issue here the ability of a generic manufacturer to get some kind of resolution of the issue of whether the patent should have been listed or not? The FDA believes they can't make that decision, and I certainly sympathize with them.

Mr. Troy is saying that these other provisions of stopping of a lawsuit up to 45 days and maybe losing your rights to sue up to 30 days, the essential point is to let the generic company be able to challenge the improper listing of a patent from which they are stopped for at least one 30-month period, maybe under existing law for more than one 30-month period. So we need some adjudication of that issue quickly, so that the public isn't denied the right for a generic drug, if it is appropriate that they should have a generic drug under the clear purpose of the law.

Mr. MURIS. There are several balls in the air here, and let me try to address at least two of them.

In terms of what would the world look like without the 30-month stay, we found, with or without litigation, it takes about 25½ months before the district court opinion or FDA approval. Obviously, they can't enter before FDA approval if there is no lawsuit, and they don't enter during the pendency of the district court litigation.

So the difference between 30 months and 25½ months is not all that significant. Thus, if you eliminated the 30-month stay, what I am——

Mr. WAXMAN. If it is a blockbuster drug, it is very significant, and why should you have something that is arbitrary? If FDA is improving in the speed at which they get drugs on the market, whether it is a brand-name drug or a generic drug, which we want to encourage, why should we have some artificial 30-month period based on a patent that wasn't appropriate to list and for which there should be any stay of a generic competitor?

I guess let me have that out there——

Mr. BILIRAKIS. The time has expired. Mr. Muris, just respond to that question, and then let's move on because we've got a panel that has been sitting here since 10 o'clock.

Mr. WAXMAN. I had that more as a rhetorical question, but I think it is an issue that needs to be addressed.

Mr. MURIS. May I respond?

Mr. BILIRAKIS. Please, briefly.

Mr. MURIS. We accepted the validity of the 30 months, and we said that, in fact, 25½ months and 30 months are not that far apart. It is true for a blockbuster drug that it would be significant.

If you wanted to reopen the question as to what was the right period of time, obviously, then you could look and say, well, 25½ months is shorter than 30 and make your decision. Again, we accepted the validity of the 30 months, the 180 days, and tried to see what the evidence bears on those issues.

Mr. BILIRAKIS. All right, the gentleman's time has expired. I think we should just consider this finishing up with this panel.

Mr. BROWN. Mr. Chairman, could I have 2 minutes to follow up with——

Mr. BILIRAKIS. Are we ever going to finish here?

Mr. BROWN. Yes, if I have my 2 minutes, we will, Mr. Chairman.

Mr. BILIRAKIS. Well, your 2 minutes will result in——

Mr. BROWN. The chairman promised Mr. Waxman a couple of minutes on a partial round.

Mr. BILIRAKIS. I understand Mr. Waxman has had considerably more than a couple of minutes. We made that promise, but——

Mr. BROWN. But, no, he had Mr. Wynn's time. Mr. Chairman, Mr. Muris said several things. I just want to——

Mr. BILIRAKIS. Without objection, the gentleman has 2 minutes.

Mr. BROWN. This is such an important——

Mr. WAXMAN. I object.

Mr. BILIRAKIS. Objection?

Mr. WAXMAN. Would the gentleman permit, if he would yield to me? Look, I was able to get additional time on Mr. Wynn's time. Mr. Brown is requesting two more. This is a complicated issue, and I don't think anybody else is going to ask for more time.

I will withdraw the objection.

Mr. BILIRAKIS. Yes, I appreciate the gentleman withdrawing, but the truth is we've got to finish sometime with this panel. We have had another panel sitting there 4½ hours. Let's be fair. The Chair yields to Mr. Brown.

Mr. BROWN. On your 25½ months versus the 30 months, first of all, I think the extra 4½ months on a drug like Prilosec or a drug that has \$3, \$4, \$5, \$6 billion in sales, there is a huge amount of money at stake for the Nation's consumers or the Nation's businesses, or whatever.

Second, I am not sure that there is any incentive to squeeze that 25½ months down when it really doesn't matter because they are getting this 30-month extension anyway.

Third, I wonder why we can approve a new drug so much more quickly and a generic drug so slowly when one would think that you could do the generic drug at least as quickly. But we have shoveled more and more money into the approval process on new drugs and we have underfunded the generic drug approval.

So couldn't we, couldn't the FDA—and I am asking Mr. Muris or maybe both of you, quickly—couldn't we get the FDA to shrink that 25½ months significantly? Then there is no longer the discussion, why should the 30-month—it doesn't matter if we repeal it because the 30-month one is arbitrary.

Second, it is not so similar in time if we can reduce that 25½ down to 18, which many say it has been, and maybe down further, if we can provide the resources for——

Mr. MURIS. But the issue is what happens in a lawsuit. What happens in a lawsuit is obviously both parties are involved.

When there is a district court lawsuit, and we found the generics win most of the cases, if that judgment dissolves the 30-month stay, as we believe it does and should, then you will have generic entry in most cases.

We have found that the generics, because they have won 13 out of 14 cases on appeal, the generics are willing to enter after a district court decision. So I think that we are mostly talking about a non-issue here. In fact, that is probably why none of these bills that I know of are talking about getting rid of the initial 30-month stay.

Mr. BROWN. Actually, the original Brown-Emerson bill does. We pursued the Senate version because we thought, if we can get Republican leadership to schedule it for a vote, we wanted to do it quickly, get the Senate version, get it back in its identical version and get it to the President.

So, no, in fact, the first bill out there, the original Schumer-McCain and the original Brown-Emerson did have elimination of the 30-month.

Mr. BILIRAKIS. The time of the gentleman has expired.

Mr. BROWN. Thank you, Mr. Chairman.

Mr. BILIRAKIS. Dr. Crawford and Mr. Muris, thank you so very much. We appreciate your patience. We customarily do have written questions that we submit to you. We would hope that you would plan to respond to those questions in a reasonable period of time.

Thank you so very kindly for being here.

Mr. CRAWFORD. Thank you.

Mr. MURIS. Thank you.

Mr. BILIRAKIS. Panel two, finally: Ms. Kathleen Jaeger, President and CEO of Generic Pharmaceutical Association; Dr. Gregory J. Glover, Ropes and Gray here in Washington, DC, on behalf of PhRMA; Dr. Sharon Levine, Associate Executive Director of The Permanente Medical Group, on behalf of RxHealthValue, and Dr. Mark Barondess of Annapolis, Maryland, Dr. Barondess being a J.D.

Well, ladies and gentlemen, the clock is set at 5 minutes. Your written statement, of course, is a part of the record. We would hope you would complement it or supplement it. We would appreciate it if you could stay as close to the 5 minutes as you can.

We will kick off, if she is ready, with Ms. Jaeger.

STATEMENTS OF KATHLEEN D. JAEGER, PRESIDENT AND CEO, GENERIC PHARMACEUTICAL ASSOCIATION; GREGORY J. GLOVER, ROPES AND GRAY, ON BEHALF OF PhRMA; SHARON LEVINE, ASSOCIATE EXECUTIVE DIRECTOR, THE PERMANENTE MEDICAL GROUP, ON BEHALF OF RxHEALTHVALUE; AND MARK A. BARONDESS

Ms. JAEGER. Chairman Bilirakis, Congressman Brown, and members of the subcommittee, thank you for the opportunity to testify on the very important subject of the refinements to the Drug Price Competition and Patent Restoration Act of 1984.

The 1984 act is a landmark consumer piece of legislation that has opened the door to prescription drug competition. In 1984, Congress determined that the balance between incentives for innovation and the opportunities for competition were out of kilter. This subcommittee and its members played a central role in the adoption of the legislation that was intended to restore this balance.

The incentive piece of the act has been extremely successful. It has yielded important new medicines and generous profits to drug companies.

On the competition side, the benefits of the act have also been significant. The percentage of prescription drugs sold in generic form has risen from 19 percent in 1984 to 47 percent today. So that generics are currently saving consumers, the Federal Government, and health care providers \$10 billion each year.

But we are losing important opportunities to save more. This is despite the fact that there's been an increase in generic usage, and the percentage of prescription drug expenditures dedicated to generics has been declining and is now at 8 percent. In other

words, 92 cents of every prescription dollar goes toward a brand product.

This is important because an increase of just 1 percent in generic utilization would save an additional \$1.3 billion. Doing simple math, an increase of just 10 percent yields \$13 billion in savings.

Relevant to today's hearing is that the balance has shifted as a result of some brand companies using innovative and creative skills to exploit the system's loopholes in order to block generic competition. One of these loopholes which we have heard a lot about, and is the subject of the FTC report, is the 30-month stay. The FTC report identified and confirmed that, indeed, abuses are occurring, and that these abuses must be addressed if goals of the act are to be preserved.

The greatest area of abuse, as I said, is the 30-month stay. Under this provision, when a generic challenges a brand patent and the brand company sues on that patent, FDA approval of the generic product is automatically blocked for 30 months. This block occurs regardless of the patent's merits.

In other words, the system bestows a financial windfall to the brand company for merely suing a generic firm, regardless of whether the patent at issue is properly listed. Inappropriate patents, patents that do not claim the brand product, cannot only trigger a 30-month stay, but in some instances result in multiple stays.

Let's look at some facts. Patent listings have increased from two patents in 1984 to on average for blockbusters today of 10 patents. Correlating to this fact is that patent challenges have increased from 2 percent of generic applications in 1984 to 1989, to 12 percent in 1990 to 1998, 20 percent in 1998 to 2000, and last year to 28 percent. There is no reason why this trend will not increase unabated.

The FTC report documents that abuse of the 30-month stay by the brand industry is a strategy used by some brand companies in the last few years to maximize profits on blockbusters. The FTC report suggests that not only will this trend get worse, but this abuse has real-world consequences.

Despite the FTC's findings, the Senate's approval of GAAP by a 78-to-21 vote, and the coalition members supporting that bill, PhRMA charges the generic industry is overstating its case. It argues that the current system works well.

Clearly, they have not put this argument to a vote by consumers, businesses, and other purchasers. PhRMA's argument ignores the single mother of an asthmatic child requiring the drug Maxar who can't get an affordable equivalent because the patent is listed, not on Maxar, the drug, but on the new container that houses Maxar.

PhRMA's argument also ignores the cancer patient who will have to pay the higher brand price for years to come because the brand company listed two patents that define how product information should be inserted into pharmacy computers, solely to block generic competition.

Another well-known example is the anti-depressant Paxil, which has annual sales of \$2 billion. The two major patents, the basic compound patent and the first-method-of-use patent, expired in 1992 and 1994, respectively. Yet, the brand company has sued a generic firm for infringement of five other patents, thereby gener-

ating five new 30-month stays, totaling 65 months, and costing consumers billions of dollars.

Like many of our coalition partners, GPhA believes a 30-month stay provision should be eliminated in its entirety, although we do endorse the one 30-month stay compromise recently passed overwhelmingly by the Senate. This compromise is also included in the House companion legislation that is currently pending before this committee.

The Congressional Budget Office reported that American consumers will save \$60 billion over the next 10 years if Congress enacts GAAP. CBO has already proven our main point of this debate. Fair competition is pro-consumer and pro-savings.

Mr. BILIRAKIS. Please summarize, Ms. Jaeger.

Ms. JAEGER. I would be pleased to.

GAAP does not change patent law. GAAP is merely a rule change, if you will, a refinement of existing law that addresses current system abuses and trends. GAAP would restore the intended balance between innovation, competition, and access. We urge the House to immediately approve legislation like H.R. 5272 and H.R. 5311. Thank you.

[The prepared statement of Kathleen D. Jaeger follows:]

PREPARED STATEMENT OF KATHLEEN D. JAEGER, PRESIDENT & CEO, GENERIC PHARMACEUTICAL ASSOCIATION

Chairman Bilirakis, Ranking Democrat Brown, and distinguished Members of the Subcommittee. My name is Kathleen Jaeger, and I am President and CEO of the Generic Pharmaceutical Association. I am also a pharmacist and an attorney, who specializes in FDA-regulatory law. Coming from a family-owned pharmacy background, I understand the critical role that both brand and generic pharmaceuticals play in our health care system. Thus, the relevant debate is not about the value of brand products or generic products—again both provide tremendous value. Rather, the issue is the need to restore predictability to the Hatch/Waxman system—to ensure that the system is fair and just for all affected parties, especially consumers.

GPhA represents manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. GPhA members manufacture more than 90 percent of all generic drug doses dispensed in the United States. Over one billion prescriptions are filled with our products every year. We are a significant segment of America's pharmaceutical manufacturers. No other industry has made, or continues to make, a greater contribution to affordable health care than the generic pharmaceutical industry.

On behalf of GPhA and its more than 140 members, I want to thank you for convening this hearing. It is critically important that we address the issues related to increasing access to prescription drugs while assuring that American consumers can afford the medicines they need. With such a short time remaining before Congress recesses, a unique opportunity exists: to pass legislation that will take a meaningful step towards reducing the cost of prescription drugs over the next decade.

Today, I will discuss the current landscape of the pharmaceutical industry, both generic and brand, and how the Federal Trade Commission (FTC) identified abuses under the present construct, with their trend analysis indicating that these abuses will only get worse in the future. The FTC report accurately diagnoses system abuses involving the 30-month stay provision among others. Congressional Representatives have proposed thoughtful and a narrowly targeted legislative solution that would address these abuses by closing several unintended loopholes in Hatch/Waxman. Legislation that is critically necessary to avoid unnecessary future expenditures, which cost consumers billions of dollars in lost savings.

I will explain why the approval by the House of Representatives of H.R. 5311 and H.R. 5272, the Greater Access to Affordable Pharmaceuticals Act ("GAAP"), would create billions of dollars in prescription drug cost savings without harming the brand pharmaceutical industry or sacrificing brand product innovation.

I will also provide compelling evidence that legislation such as this would restore the balance between brand-name innovation and generic competition that lies at the

heart of the Hatch/Waxman Act. In doing so, I will review the positions of the Congressional Budget Office and the FTC, which confirm the need for legislative intervention in this area.

I. BACKGROUND—GENERICIS SAVE CONSUMERS BILLIONS EACH YEAR

I will start with a brief overview of the contribution of the American generic pharmaceutical industry.

The Drug Price Competition and Patent Term Restoration Act of 1984, also known as Hatch/Waxman, extended product monopolies on brand drugs in exchange for the establishment of a regulatory process for affordable medicines—an Act that created the modern generic pharmaceutical industry. This process was designed to streamline the approval process for generic drugs, which can only enter the market after the expiration of all valid and non-infringed patents that protect the equivalent brand drug products.

Since 1984, the use of generic pharmaceutical products saves millions of dollars for consumers and taxpayers each and every day. These savings amount to more than \$10 billion dollars in lower health care costs each year. For the last couple of years, about 45 percent of all prescriptions were filled with generic drugs. But while nearly one in every two prescriptions was filled with a generic drug, only about 8 percent of all dollars spent on drugs were spent on generic medicines. Conversely, brand name prescription drugs represented 53 percent of all prescriptions but consumed approximately 92 percent of all drug therapy dollars spent. The top ten brand pharmaceutical companies accounted for 61 percent of all pharmaceutical sales.

These numbers reveal a stark reality: brand name prescription drugs exceed the cost of generics by almost ten-fold, and brand companies dominate the marketplace in terms of dollars spent on prescription drugs.

Let's look at these same statistics from another perspective; namely, that of the patient or payer. The average price of a prescription dispensed with a generic drug in 2001 was \$16.85. The average price of a prescription dispensed with a brand name drug in 2001 was \$72. That is an average savings of 76 percent when a generic product is substituted for a brand product.

While generic substitution has increased from 19 percent in 1984 to 47 percent in 2000, the amount of money spent on generic drugs as a percentage of overall dollars spent on medicines has declined five percentage points, from 12 percent to 7.5 percent, over the past five years. So, consumers used more generics and spent less on them. But at the same time, the cost of prescription drugs continued to increase at double-digit rates.

Currently, 7,602 of the 10,375 drugs listed in the FDA's Orange Book (which identifies therapeutically equivalent generic drugs and their brand counterparts) are available in generic form. Over the next decade, a number of the most well-known brand name pharmaceuticals will lose patent protection, theoretically allowing the introduction of more affordable generic versions of these blockbuster products. Within the next three years, 27 brand name pharmaceuticals with annual sales of more than \$37 billion should go off patent. If the law and regulatory system were working as intended, this development would create an important opportunity to save critical health care dollars.

II. THE TREMENDOUS SAVINGS THAT GENERICIS OFFER CONSUMERS, THE FEDERAL GOVERNMENT AND OTHER INSTITUTIONAL HEALTH CARE PAYERS

As I previously discussed, the generic prescription utilization rate is 47 percent. An increase of 1 percent in this utilization rate would generate payer savings of \$1.3 billion each year. An increase of 10 percent would save \$13 billion.¹ We cannot afford to miss this opportunity.

A. Brand Pharmaceutical Innovation

The debate over restoring the balance created under Hatch/Waxman has been falsely cast as a threat to brand pharmaceutical innovation. We endorse the brand pharmaceutical industry's role in discovering new drugs, and the societal value of a patent system that fosters the development of new innovative medicines. However, we reject—as do so many others involved in our broad-based, bi-partisan coalition—the notion that the status quo is fair and consistent with the aims of the Hatch/Waxman Act. To the contrary, the current system allows for the exploitation of unintended loopholes to preserve profits and monopolies, long after valid patents and patent extensions have expired, at the expense of the American consumer.

¹ Tim R. Covington, Executive Director of The Managed Care Institute at Samford University.

One of the best ways to promote innovation, to provide an incentive to develop the next medical breakthrough product, is to foster competition. Allowing a brand product to have unlimited monopoly protection distorts the incentive, and results in the adoption of a brand preservation strategy, rather than an innovation strategy.

The intent of Hatch/Waxman was to define and establish a natural and limited period of monopoly protection, in recognition of the societal value of brand innovation. However, after the expiration of that monopoly, more affordable generic alternatives should have unfettered access to the marketplace. But in recent years, loopholes in the Act have been identified and manipulated to expand this protection well beyond what the drafters of Hatch/Waxman intended or even imagined, and to deny consumers access to affordable medicines. It is time to recognize that these efforts are nothing more than attempts at monopoly extensions, which actually harm innovation and penalize consumers in various ways.

A number of organizations have in recent years explored whether generic competition poses a risk to brand pharmaceutical innovation and the “search for cures.” The results of these separate analyses are consistent. Competition is good for innovation, and the brand pharmaceutical industry has thrived since 1984.²

Moreover, one such study also concluded that after Hatch/Waxman extensions were added, 44 percent of the drugs examined had effective patent lengths of 14 years or more. Equally important was the observation in another study that brand manufacturers manage patent protection for blockbusters more aggressively resulting in longer effective patent lengths.³

The brand pharmaceutical industry’s opposition to reforming Hatch/Waxman is not about the threat to innovation; it is about a threat to profits.

B. The Current System Is Being Abused To The Detriment of American Consumers

As previously noted, Hatch/Waxman guaranteed brand companies a period of market exclusivity to recoup their investment in research and development. It also established a specific period of exclusivity, including a five-year patent extension for most drugs, but it was also intended to create a regulatory system that allowed the generic manufacturers to bring their products to market immediately upon expiration of the brand patents.

Over the past decade, some aggressive brand companies, enjoying the profits of market exclusivity, have gamed the system to obtain unintended extensions to this exclusivity. This has hurt consumers and taxpayers, and upset the balance between innovation and competition that was initially created under Hatch/Waxman. The cost of these activities has been in the billions of dollars. It should be noted that these games have not been played by all the brand companies. A number of the largest and most research-oriented brand companies have declined to exploit the recently discovered loopholes as a way of extending their patents.⁴

The recently released FTC Report on “Generic Drug Entry Prior to Patent Expiration” (the “FTC Report”) identified gaming of the Hatch/Waxman patent challenge process by brand companies and analyzed its impact on pharmaceutical competition. The over-arching conclusion of the report is that abuses of the current system have cost consumers billions in lost savings, and may cost even more if not remedied by legislative action. The primary tool for the abuse has been the automatic 30-month stay provision. This statutory provision bestows brand companies free 30-month injunctions regardless of the merits of the case, which bar the Food and Drug Administration (FDA) from approving generic competitor’s products.

The 30-month stay is available for all patents that are “listed” by the brand company in FDA’s “Orange Book,” a publication containing a list of patents that cover approved drugs. Over the past several years, certain brand companies have discovered that FDA does not police patent listings. FDA takes the position that it has no authority, nor the expertise to determine if patents submitted for listing meet the statutory requirement of claiming the approved brand drug product.⁵ In other words, even if a brand company lists a patent that on its face does not cover the brand product, FDA will automatically list the patent as long as the brand company maintains its listing. Moreover, courts have found that no legal means exist for generic firms to challenge improperly listed patents. Still, this lack of balance, coupled with the windfall of the 30-month stay, provides a perverse incentive for brand com-

² Congressional Budget Office, 1998; *How Increased Competition From Generic Drugs has Affected Returns in the Pharmaceutical Industry*; Pharmaceutical R&D: Costs, Risks & Rewards, 1993.

³ Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks & Rewards*, 1993.

⁴ Merck; Novartis, Pharmacia to name a few.

⁵ FDA’s brief (dated September 23, 2002), filed in *Apotex, Inc. v. Thompson* (No. 02–1295). FDA also opined that if there is an “enforcement gap,” redress lies with Congress, not FDA or the courts. *Id.* at 35.

panies to adopt an over-reaching patent listing strategy for large selling “blockbuster” drugs. The average number of patents listed for each blockbuster has increased from 2 in 1984, when Hatch/Waxman was enacted, to 10 today.

The driving force behind the substantial increase in patent listings is a free 30-month stay, which occurs in 85 percent of the cases when the brand company sues a generic. The only reason for listing patents that do not claim the brand drug, and therefore have little or no chance of surviving a challenge by a generic competitor, is to obtain a financial windfall that flows from the free stay. This strategy is evidenced by the dramatic increase in the number of patent listings and, correspondingly, in the number of patent challenges in order to bring generic drugs to market. These patent challenges have increased from 2 percent of all generic applications in 1984-1989, to 12 percent in 1990-1998, to 20 percent in 1998-2000, and to 28 percent in 2001.

FTC also identified the fact that multiple patent listings result in protracted litigation, causing significant consumer delay. By listing multiple patents, brand companies can, among other things, obfuscate the proceedings to insulate a certain patent from adjudication. Equally important is the fact that they also can design their patent strategy to yield several consecutive 30-month stays. The FTC, in its report, found that singularly, and in combination, the automatic 30-month stay has “real world consequences” for consumers. This activity is clearly a trend that is destined to continue and most likely intensify if not checked.

From a consumer’s perspective, the most alarming aspect of these abuses is that they involve almost exclusively the most popular, and sometimes the most needed drug products. Specifically, we are seeing the most abuse with those drug products with annual sales over \$500 million. The cost to an individual healthcare plan can be significant; the cost the healthcare system can be enormous. For example, General Motors estimates that if five pharmaceutical blockbuster patents scheduled to expire are extended, they will see increased prescription drugs costs in excess of \$204 million during the delay of generic entry. Similar losses are being felt by the federal and state governments as they struggle to meet their budgets and provide Medicaid coverage.

When one considers the totality of the circumstances surrounding these abuses, several facts emerge.

- First, absent congressional action, the future is likely to be worse. Given the current trend, and the financial windfall that brand companies can achieve through the exploitation of these loopholes, the abuses are almost certain to increase over the next decade.
- Second, more patents are appearing, and will continue to appear, in the Orange Book and these additional patents will cause significant delays in the availability of lower cost generic drugs.
- Third, these abuses have seriously degraded the predictability of generic drug approval that was a cornerstone of Hatch/Waxman. This loss has already resulted in tremendous harm to the nation’s health care system, especially to Federal, state, and private health care providers who are struggling to keep up the escalating cost of prescription drugs. It also undermines the ability of generic companies to manage their businesses efficiently.
- Lastly, 27 blockbuster drugs are “scheduled” to come off patent in the next five years. If the loopholes in the 30-month stay and patent listing provisions are not closed, a delay in the availability of low cost equivalents of these drugs is almost certain to occur.

C. The FTC Report Confirms The Brand-Name Abuses and Supports The Modest Reform

In response to alleged abuses, FTC was asked to investigate the operation of the Hatch/Waxman patent challenge process. FTC looked at the 30-month automatic stay, and at the 180-day generic exclusivity incentive that is available to generic companies that are first in time to challenge improper, weak, or invalid brand-name patents. This past July, the FTC issued its final report. Its findings clearly confirm that:

- (1) the 30-month stay is being abused and is delaying competition; and
- (2) the 180-day exclusivity provision is an efficient means of eliminating illegitimate barriers to competition.

The FTC found that the 30-month stay provision in of itself is problematic. FTC also found that subsequent 30-month stays unfairly block generic competition, particularly since none of the patents supporting those stays had been held to be valid.

Accordingly, like many of our coalition partners, GPhA believes that a 30-month stay provision should be eliminated in its entirety, although we did endorse the one 30-month compromise recently passed by the Senate. Contrary to the findings of the

FTC, which focused on past FDA practices, we believe that in the future FDA will take significantly less than 25 months to review and approve generic drug applications. The dramatic improvements in review of brand applications (which are now completed in about 6-10 months) demonstrate that this is clearly possible. Moreover, the long review times in the past may be explained, in part, by the fact that often a generic will not be eligible for marketing after its application is filed, because the application was filed in advance of the expiration of a valid patent or because the 30-month stay blocks approval. If the 30-month stay provision was eliminated, there would be new incentives for FDA and the generic companies to work to expedite review and approval of generic drugs.

Additionally, FTC found that, since 1998, brand companies are listing more and more patents for drugs with substantial annual sales. Prior to 1998, patent litigation for most blockbuster drugs involved only 1 or 2 patents. Since 1998, 5 of the 8 blockbuster drug cases considered by FTC involved 3 or more patents. As FTC observed, “with additional patents to be litigated, the average time to obtain a court decision has increased.”⁶ Furthermore, FTC found that many of these new patents do not meet the statutory requirements for listing in FDA’s Orange Book. We draw the Committee’s attention to Appendix H of FTC’s report, where FTC analyzes three types of patent listing abuses: patents not claiming the approved drug or an approved use of the drug; product-by-process patents⁷; and double patenting⁸. FTC’s efforts to take enforcement action to address the anticompetitive effects of these improperly listed patents may have been significantly hindered by FDA’s failure to respond to a 2001 FTC petition requesting guidance on the patent listing requirements.

FTC noted that patent listing abuses are being fueled by (1) the lack of patent listing policing and (2) the total lack of a statutory mechanism to “delist” patents once they are submitted for inclusion in the Orange Book. The courts, supported by FDA, have held that there is no private right of action under the Patent Act or the Federal Food, Drug, and Cosmetic Act to have a patent “delisted,” even where it is obvious that the patent does not meet the requirements for listing.⁹ In other words, the brand company may illegally list a patent (which, significantly, is a prerequisite to a paragraph IV certification and triggers the 30-month stay provision), but the FDA alleges that it lacks the authority to assess the appropriateness of patent listings. Yet, the courts have held that the generic company cannot challenge the listing in court. The GAAP Act corrects this inequity by permitting the generics to bring a suit in court.

Another activity observed by FTC is the “stacking” of multiple 30-month stays. As discussed above, this practice consists of listing as many patents as possible once a patent battle has begun in order to obtain successive 30-month stays that keep the generic competition out of the market. FTC found that brand companies have just recently discovered the potentially unlimited monopoly profits that can be reaped by taking advantage of the lack of a patent delisting mechanism and the automatic 30-month stay. According to FTC, the “stacking” of multiple 30-month stays has delayed generic approval for not 30 months, but for 34 to 70 months—4 to 40 months *beyond* the first 30-month stay. Furthermore, six of the eight “stacking” abuses cited by FTC occurred since 1998, and all occurred since 1996—demonstrating that the discovery of this loophole is relatively new, but steadily on the rise.

FTC also correctly observed that, like all other patent owners, brand companies can prevent generic marketing by demonstrating entitlement to a preliminary injunction. FTC further concluded that there were no instances where a generic drug entered the market and was later found to be infringing on the brand’s patent—so in essence, the generic industry self-polices itself given the potential liability exposure.

In regard to patent challenges, the FTC data confirms that patent challenges by generic companies under Hatch/Waxman result in greater competition and consumer access to affordable medicine. FTC’s analysis revealed that generics are **winning nearly 75 percent** of the patent cases and, therefore, are bringing “appro-

⁶FTC Report at p. 37.

⁷These are patents that are the functional equivalent of “process patents,” which are specifically prohibited from listing in the Orange Book.

⁸These are patents that claim the same invention as a prior patent, but are nevertheless issued by the Patent and Trademark Office because the patent applicant agrees to have the new patent expire on the same date as the earlier patent.

⁹*Mylan Pharm. v. Shalala*, 81 F.Supp.2d 3 (D.D.C. 2000); *AAIPhRMA v. Thompson* (CA-01-153-F) July 10, 2002 (Until Congress takes further action to address the enforcement gap in Hatch/Waxman’s patent listing provisions, the FDA may persist in its purely ministerial approach to the Orange Book Listing Process.).

appropriate challenges” to brand patents. This percentage would be even larger if one included some of the patent suit settlements that were the equivalent of a generic victory. This is compelling evidence that, in the overwhelming majority of cases, patent challenges brought under Hatch/Waxman are removing illegitimate barriers to competition and making a real difference in the cost of prescription drugs. Thus, the FTC Report is entirely consistent with eliminating 30-month stay provision from Hatch-Waxman.

D. Reform is Needed Now

Americans need relief from out of control prescription drug costs. Generics can help. GAAP will not provide all the answers, but it does represent a constructive step in closing loopholes that delay the introduction of generic drugs after the valid brand patents and corresponding patent extensions have long expired.

In 2000, NIHCM released a study that analyzed the issue of brand innovation and patent extensions. The study suggested that changes in the law over the last two decades have increased by at least 50 percent the effective patent life for new drugs. That means drug companies have, in addition to five years of patent restoration time, recovered an extra four or five years to reap profits before low-priced generics enter the market. The NIHCM study concluded that delays in generic competition are forcing customers to incur billions of dollars in prescription drug costs they otherwise may not have paid.

In opposition, PhRMA has been using a chart to bolster its case. This chart allegedly indicates that reform of Hatch-Waxman is not necessary by showing the cumulative value of brand products coming off patent in the next ten years. What PhRMA neglects to mention for a multitude of reasons—one of which involves 30-month stays—is that 20 of the 30 possible products that should have gone off patent in 2000 failed to have generic competition during that year. This represented \$5.4 billion in sales. Likewise, in 2001, generic competition did not commence for 23 of the 26 products, representing \$11.4 billion in sales.

III. HIGHLIGHTS OF GAAP LEGISLATION

GAAP achieves significant savings by closing loopholes in the current laws that allow brand name drug companies to block generic drug approval and thereby delay consumers’ access to more affordable medicine.

The significant provisions of GAAP, which the Senate overwhelmingly passed by a vote of 78-21, include:

- **Limiting brand drug companies to a single 30-month automatic stay of generic drug approvals.** When a generic applicant challenges a patent, and is subsequently sued by the brand name drug company, there is an automatic 30-month stay, in essence a free preliminary injunction, which prevents FDA from approving the generic product. In other words, the system bestows a financial windfall to the brand company for merely suing the generic—regardless of the fact that brand companies lose these lawsuits nearly 75 percent of the time. This 30-month stay of course is unique to the pharmaceutical industry with respect to classical drug products. To obtain a preliminary injunction against a competitor in all other industrial sectors, including antibiotic and medical device cases, patent owners must meet a significant burden of establishing the likelihood of success on **the merits of the patent** before a competitor’s product is kept off the market. Thus, because the thirty-month stay is not based on the patent’s merits, it can be quite problematic in and of itself, resulting in needless health care costs. In addition, the brand company can currently list multiple patents while a lawsuit is ongoing, resulting in additional 30-month stays for each new listing. This can delay generic approval virtually indefinitely. GAAP would limit brand companies to a single 30-month stay for the patents that are listed in the Orange Book when the brand drug was originally approved. For all other patents, GAAP provides an easier preliminary injunction standard by which brand companies can seek to keep generic competitors off the market during the litigation.
- **Providing an accurate list of patents for brand name drugs.** There is currently no method for correcting the information in the FDA Orange Book, the document that lists the patents that protect brand drugs from generic competition. The courts have held that there is no right to challenge a patent listing and FDA alleges it has no authority in this area. The FTC, in its recent report, noted several examples where patents that “raised legitimate listability questions” were listed solely to generate 30-month stays. GAAP allows the private sector to insure the correctness of patent listings by giving generic applicants

and patent owners the right to sue brand companies to correct improper patent listings in the Orange Book.

- **Providing a complete list of patents for brand name drugs.** The proper listing of all relevant patents is essential to providing timely access to affordable medicine. This will be especially true when the 30-month stay loophole is closed. Without the potential for a 30-month stay, brand companies may be encouraged to NOT list their patents and therefore shift the litigation outside of the Hatch/Waxman system. By doing so, brand companies could wait longer to sue, thereby delaying the timely resolution of patent issues. GAAP would address this potential future loophole by preventing brand companies from suing generic manufacturers over patents that are not listed in a timely manner. This imposes little or no burden on brand drug companies, but is imperative to the efficient operation of Hatch/Waxman to facilitate the timely access of affordable pharmaceuticals.
- **Ensuring the timely resolution of patent disputes.** Currently, the potential for a free 30-month stay drives brand companies to sue generics within 45 days of being notified of a patent challenge. When the free 30-month stay is taken away for patents listed after the brand approval, brand companies may seek to make an end-run around the system by waiting until the eve of generic approval before bringing their lawsuit. This would have the effect of keeping generic competition out of the market because it would create too much risk for the generic company to introduce the product. GAAP requires generic applicants to provide a detailed notice to brand companies of their intent to market a lower priced version of the drug. GAAP also requires the brand company to sue the generic company within 45 days of receiving this notice or lose its right to sue that particular company. This provision is essential to prevent future gaming of the system.
- **Preserving the incentive to challenge patents.** The current law grants 180 days of exclusive generic marketing to the first generic company to successfully challenge a brand drug patent. As the FTC noted in its recent report, the generic industry has been extremely successful in selecting weak and invalid patents to challenge. As a result, consumers have received affordable versions of blockbuster drugs such as Prozac years ahead of when they otherwise would have been available. However, recent court decisions have drastically reduced the value of this incentive by triggering the exclusive marketing period following the initial court ruling in the case. As a result, it is possible for the 180-day generic exclusivity period to expire before the appeals process is completed. GAAP fixes this by moving the triggering event out to the date of an appeals court decision.
- **Forfeiture of 180-Day Exclusivity.** The current law does not adequately address situations where the first generic challenger does not, or cannot, go to market after the resolution of the lawsuit. GAAP provides for the forfeiture of the first challenger's exclusive marketing period if they do not go to market within 60 days of specified events.

CONCLUSION

The Congressional Budget Office reported that American consumers will save 60 billion dollars over the next ten years if Congress enacts the GAAP bill currently under debate. CBO has already proven our main point in this debate: fair competition is pro-consumer and pro-savings. Moreover, these savings will make a prescription drug benefit more affordable.

The Generic Pharmaceutical Association believes that modest legislative fixes contained in GAAP could stop abuses and restore the balance between innovation, competition and access originally sought in the Hatch-Waxman Act. GAAP does not rewrite Hatch/Waxman. GAAP does not change patent law. GAAP simply restores balance to a system created two decades ago. It is a rule change, if you will, a refinement of existing law, not a rewrite of Hatch/Waxman.

I would be happy to answer any questions.

Mr. BILIRAKIS. Thank you. Dr. Glover, please proceed, sir.

STATEMENT OF GREGORY J. GLOVER

Mr. GLOVER. Mr. Chairman and members of the committee, on behalf of the Pharmaceutical Research and Manufacturers of America, I am pleased to appear at this hearing today. I am here to discuss the importance of innovation and competition in maintaining

patent incentives for discovering new medicines and the critical, highly successful role of the Hatch-Waxman Act in fostering a competitive market that drives innovation.

Competition in the pharmaceutical industry is robust. Innovation results in new products that compete with products of other research-based companies, thereby providing patients with important therapeutic options. Thanks to the Hatch-Waxman Act, the generic industry's share of the prescription drug market has jumped from less than 20 percent in 1984 to almost 50 percent today. This demonstrates the system is working as intended by Congress.

However, we are concerned that the current debate is heading toward eroding legitimate intellectual property rights and legitimate efforts to enforce those rights. The findings of the Federal Trade Commission do not demonstrate patterns of widespread abuse of the Hatch-Waxman Act, nor do they justify the sweeping measures included in pending legislation.

The FTC reported concerns about only eight cases out of more than 8,000 generic drug applications since 1984, less than one-tenth of 1 percent. Any congressional legislation that works 99.9 percent of the time should be heralded as an unqualified success.

As the FTC explains in the report's preamble, the study addresses only consumer access to the generic drugs. It does not address the Hatch-Waxman objective of promoting innovation. This limited focus does not address the need to maintain current incentives for innovation and the creation of new treatments and cures.

One mechanism for preserving these incentives is the 30-month stay. During this time period the FDA cannot grant final market approval for a generic product that is involved in timely initiated patent litigation. Contrary to many assertions, the 30-month stay does not extend the patent.

Currently pending legislation would deny the 30-month stay for any patent filed with FDA more than 30 days after new drug approval. The FTC report suggests a very different, but still flawed, policy that would deny a 30-month stay to any patent listed in the Orange Book after the relevant ANDA was filed.

Both limitations are arbitrary and are based on a fictional version of research and development, where innovation for a product ceases as soon as the innovator begins the FDA approval process. The reality is that pioneer companies continue to innovate even after the FDA approval process begins. Companies continue to innovate to improve the side effects profile, improve stability, increase the efficiency of drug delivery, improve dosage regimens, and develop changes in dosage forms.

The patents are filed when the innovation occurs. However, depending on the timing of the innovation and the review processes of the Patent and Trademark Office, many, if not all, of those patents can be issued more than 30 days after NDA approval.

In addition, the legislative proposals include several provisions that extinguish the patent owner's rights to enforce its patents, either inside or outside the context of the Hatch-Waxman Act. These provisions demonstrate that the patent system itself is at the heart of the debate, patent protection that is guaranteed by the United States Constitution.

Indeed, purported benefits of legislation now before Congress will prove elusive because the increased availability and use of innovative medicines is what really helps reduce the cost of overall health care. As the Patent and Trademark Office wrote in a July 30 letter to Senator Hatch regarding the Senate's proposal, quote, "This bill would likely do the opposite of what its title suggests by limiting access to cutting-edge drugs, decreasing innovation, and ultimately harming the quality of treatments available to patients."

Continuing attacks on patent rights will lead to less consumer choice and decreased availability of new drugs and will undermine the careful balance of the Hatch-Waxman Act that protects legitimate patent rights while facilitating the marketing of generic drugs. Thank you.

[The prepared statement of Gregory J. Glover follows:]

PREPARED STATEMENT OF GREGORY J. GLOVER, ON BEHALF OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

Mr. Chairman and Members of the Committee: On behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA), I am pleased to appear at this hearing today on the Hatch-Waxman Act. I am a physician and an attorney with the law firm of Ropes & Gray, specializing in the relationship between intellectual-property and FDA regulatory law. PhRMA represents the country's major research-based pharmaceutical and biotechnology companies. Having invested over \$30 billion in 2001 alone in discovering and developing new medicines, PhRMA companies lead the way in the search for new treatments and cures that enable patients to live longer, healthier, and more productive lives.

INTRODUCTION

I am here to discuss the importance to innovation and competition of maintaining patent incentives for discovering new medicines and the critical, highly successful role of the Hatch-Waxman Act in fostering a competitive market that drives innovation for pharmaceutical development. Competition in the pharmaceutical industry is robust. Innovation results in new products that compete with products of other research-based companies in given therapeutic areas. Different patented medicines to reduce cholesterol and limit blood pressure are just two examples of strong competition between products within therapeutic classes. Even before generic competition occurs, competition from other innovator products takes place, providing patients with various therapeutic options.

In addition, innovation promotes competition between research-based companies and generic companies by providing new treatments and cures for generic companies to copy. As we all recognize, it is the function and business model of generic companies to copy products developed by research-based companies. Current interpretations of the 180-day generic drug exclusivity period encourage the quick filing of ANDAs containing a Paragraph IV certification to challenge the pioneer patent as soon as possible after the NDA has been approved. In many cases, generic manufacturers apply as early as 48 months after approval of the pioneer product. The result is that generics come onto the market even earlier than anticipated by Hatch-Waxman.

This highly competitive environment rests on a bedrock of innovation from the pharmaceutical industry. To the extent innovation does not occur, research-based companies and generics alike will have fewer new products, less competition will result, and more importantly, patients will wait longer for future treatments and cures.

Let me say upfront that the research-based pharmaceutical industry recognizes that generic drugs play an important role in health care. The Hatch-Waxman Act also acknowledges the important role of generics. And, because of that Act, the generic industry's share of the prescription drug market has jumped from less than 20 percent to almost 50 percent today. This marketplace shift demonstrates that the system is working as intended by Congress by maintaining incentives both for research on new drugs and for generic copies of older drugs.

However, we are concerned that the current debate is heading toward eroding legitimate intellectual property rights and legitimate efforts to enforce those rights. Today, we want to respond to frequent claims that it is anti-competitive for pioneer

companies to seek and obtain intellectual property protections for their innovations and to protect those presumptively valid rights under the provisions of the Hatch-Waxman Act and the patent law.

The findings of the Federal Trade Commission, published in its report that is the subject of today's hearing, do not support either the allegations of widespread abuse of Hatch-Waxman and patent law or the sweeping measures included in legislation pending before Congress. The FTC study focused on eight cases of concern to the Commission—out of more than 8,000 generic drug applications since 1984 under the Hatch-Waxman Act—less than one-tenth of one percent. Any Congressional legislation that works 99.9% of the time should be heralded an unqualified success.

RESPONSE TO ALLEGED ABUSES

I would like to turn now to some of the alleged abuses raised by the generic industry.

1. There has been a lot of talk about a pioneer company that supposedly had a patent on a brown bottle. The allegation is simply false. The brown bottle was described as one of many ways to protect the drug from being degraded by light, a significant concern for this drug. Indeed, in the litigation in question, the court specifically held that “no brown bottle appears as part of the claim,” and focused instead on “[the patent claiming] a composition for treating cancer with cisplatin.” The court's ruling that the invention in question was an obvious modification of prior patents in light of the scope and content of the prior art was the result of a complex analysis of patentability standards, a judicial determination legitimately and appropriately sought and provided.

2. There have been complaints about a pioneer patent on the scoring of a pill. However, the scoring was an important element of the dosing regimen for the drug. Indeed, it was so important that the generic manufacturer tried to work around the patent by making minor modifications to the scoring pattern. The generic industry cannot seriously maintain that the patent is frivolous when it has worked so hard to recreate the innovation that is covered by the patent.

3. There are allegations that patents claiming particular uses of Wellbutrin IR® stalled competition for one of the forms of Wellbutrin IR® for five years. However, since October 2000, there have been four generic versions of the drug on the market. The patents in question were never challenged by any generic.

4. The pioneer for Nicorette® has also been criticized unfairly for patenting flavors in addition to its original non-flavored product. But the pioneer only received a period of exclusivity for the first approved form of flavored Nicorette® because the FDA required additional studies demonstrating that a flavored product did not create an increased risk of nicotine addiction. The period of exclusivity did not apply to the initial form of (non-flavored) Nicorette®.

5. There have also been accusations about a pioneer improperly extending exclusivity for Prilosec®, asserting that generic competition should have begun when the patent claiming the drug's active ingredient expired on October 5, 2001. I want to review the facts of this situation, which simply do not support the rhetoric.

In 1998, AstraZeneca filed patent infringement cases to enforce its rights under certain patents that claim among other things the Prilosec® formulation. Prilosec's® active ingredient, omeprazole, by itself does not make an effective drug. To work, omeprazole must be absorbed in the small intestine, but the chemical is fragile and normally destroyed by stomach acid and decomposes quickly upon storage. To get the active ingredient safely through the stomach to the intestine, AstraZeneca's scientists had to come up with a way to shield the omeprazole from the stomach acid that would destroy it and to keep the drug from degrading. The solution was the innovative formulation.

The reason for the absence of generic products has nothing to do with any Hatch-Waxman-related activity. Although there are a number of patent infringement suits currently pending, there are no 30-month stays blocking generic approval. In fact, Andrx, one of the ANDA applicants has had FDA approval to market its drug for nearly eleven months, since November 16, 2001. Andrx's failure to market its approved product is not based on a 30-month stay, but on its own business decisions regarding when and how to prepare for commercial marketing.

6. Another drug on the list of alleged abuses is Paxil®. Paxil® was approved by the FDA in 1992 and first sold in 1993. Generic competitors wishing to copy this drug launched patent challenges on the drug in 1998—little more than 5 years after the drug was on the market. All of the other patents the pioneer has listed will expire before the initial patent covering the active ingredient. Further, if the pioneer successfully enforces its patents in court, generics can enter the market in 2007—no more than 14 years from when the drug was first marketed.

7. Finally, there have been allegations of an instance where a pioneer attempted to patent the color of a pill. We have not yet been able to find any alleged patent on pill color, and hope that the generic industry can clarify this allegation or retract it.

None of these examples represents abuse of the Hatch-Waxman Act, and several of these examples have nothing to do with the Hatch-Waxman Act at all. What these examples illustrate is that there is fundamental unhappiness with patent protection itself—protection that is guaranteed by the United States Constitution.

ANTI-COMPETITIVE PRACTICES IN THE MARKETPLACE

We are also concerned about the highly selective approach to discussing anti-competitive conduct. For example, the debate about the status of competition in the marketplace often does not include a discussion of the anti-competitive effect of the 180-day generic drug exclusivity. This provision assures that the first generic company to begin commercial marketing of a copy will not face other generic competition for the first 180 days its copy is on the market.

The 180-day exclusivity period awarded to qualifying generic patent challengers allows generic companies the opportunity to make significant profits during their period of exclusivity. But it is not at all clear that this 180-day exclusivity period is in fact needed as an incentive to bring generic drugs to market. Even without it, the generic copy business offers significant financial rewards—that's why 18 generic companies now have approval to market generic copies of Prozac® even though only five received 180-day exclusivity. Furthermore, where the generic firm is able to show that its product does not infringe the pioneer product, but cannot demonstrate the invalidity of the patent, its 180-day exclusivity provides little public benefit and is essentially a windfall to that generic.

FTC REPORT IS MORE APPROPRIATE BASIS FOR SERIOUS DISCUSSION

While the FTC report does not identify patterns of abuse, the report discusses circumstances that might give rise to abuses and proposes limited adjustments to address these circumstances. The FTC has concluded that preemptive adjustments should be pursued as an alternative to relying on antitrust enforcement to address any actual abuse should it arise.

Having said that, the FTC explains in the report's preamble, the report addresses only consumer access to generic drugs; it does not address the Hatch-Waxman objective of promoting innovation. Accordingly, the FTC report focuses on only half of the story. By considering solely consumer access to generic drugs, the study focuses on copying existing drugs rather than maintaining current incentives for innovation and the creation of new cures and treatments. In short, despite having found no patterns of abuse and not having considered potential impacts on innovation (which is the role of the Patent and Trademark Office), the FTC has proposed limited changes to a highly successful regime at the risk of harming innovation. Even with this limited focus and set of priorities, the FTC study does not support the radical changes encompassed in the bills pending before Congress.

PROPOSED "PATENT REFORM" LEGISLATION (S. 812, H.R. 5311, HR. 1862)

The legislation pending in Congress reflects a focus on the 30-month period in which the FDA cannot grant final market approval for a generic product that is involved in timely initiated patent litigation. We must bear in mind that the Hatch-Waxman Act requires the pioneer to wait until the generic manufacturer files its patent challenge before bringing this suit. This unique Hatch-Waxman benefit to generic drug manufacturers—giving the generic drug manufacturer the use of what otherwise would be patent-protected pioneer medicine data to obtain bioequivalency data for their FDA applications—is often forgotten in this debate.

Currently pending legislation would deny the 30-month stay for any patent filed with FDA more than 30 days after new drug approval. Remarkably, this even encompasses patents filed many years prior to FDA approval, but not issued until long after FDA approval. The FTC report suggests a very different, but still flawed policy that would deny a 30-month stay to any patent filed after the relevant ANDA was filed. Both limitations are arbitrary, and neither approach recognizes a corresponding need to modify the application of the patent infringement exemption. Both approaches fail to recognize the need to provide pioneers with a viable means to protect their patent rights. Both also fail to recognize that the current law on 180-day generic drug exclusivity encourages generic applicants to file patent challenges as soon as possible—even when they have no basis for a patent challenge and even when they have an inadequate application that they will need to fix later.

Furthermore, the legislation's limitation of the 30-month stay is largely based on a fictional version of research and development where innovation for a product ceases as soon as a pioneer has an approved version of that product. Therefore, nearly all patents related to the product would be issued by the Patent and Trademark Office (PTO) by the time of NDA approval. Further, drugs that receive fast-track approvals—because they represent significant improvements in the treatment of life-threatening diseases—would not get the full benefits of the Hatch-Waxman Act protections. Real examples of patents for drugs that received fast-track approvals and would not receive the full patent protections under the generic industry's proposed changes to the Hatch-Waxman Act include AZT, the first product approved for treating AIDS, and some protease inhibitors, the current state-of-the-art treatment for HIV. Other products that would be denied full protection under the generic industry proposals are important drugs for cardiovascular diseases and mental health disorders.

This scenario bears no relation to the real world of research-based science. The reality is that pioneer companies do not stop innovating once the approval process for a product begins. As countless examples demonstrate, pioneer companies continue to innovate after beginning the approval process for a product to improve the side-effects profile, improve stability, increase the efficiency of drug delivery, improve dosage regimens, and develop changes in dosage forms. The patents are filed when the innovation occurs. However, depending on the timing of the innovation and the review process at the Patent and Trademark Office, many if not all, of these patents from continuing innovation can issue more than 30 days after NDA approval. Yet, the legislative proposals would deny these patents the full protection of the Hatch-Waxman Act while, at the same time, continuing to make these patents subject to the patent infringement exemption.

In addition to the provisions on the 30-month stay, the legislative proposals include several provisions that extinguish the patent owner's right to enforce its patents—either inside or outside the context of the Hatch-Waxman Act. These provisions support my earlier statement that the heart of the complaints in the current debate are about the patent system itself. PhRMA urges Congress to recognize that playing games with the patent protections of the Hatch-Waxman Act for the benefit of generic profits and short-term cost savings does gamble on jeopardizing the incentive for the important and risky investments in future treatments and cures that are undertaken by the research-based pharmaceutical industry.

Indeed, the short-term benefits of the legislative proposals now before Congress will prove elusive because the increased availability and use of innovative medicines is a true driver of reduced overall healthcare costs. There are many examples of rapid improvements in medicines in recent years that, while leading to increased expenditures on medicines, also have led to far better results for patients, and often avoidance of much costlier hospitalizations, emergency care, and nursing home admissions. For instance, innovations in recent years have brought us both improvements in medicines and the first medicines to treat Alzheimer's Disease, diabetes, asthma, depression, AIDS, various types of cancer, and heart disease. These medicines—which save and improve lives and allow people to continue work rather than struggle with disability—are all products of our strong patent system that protects intellectual property rights, not a weak one that fails to do so.

CONCLUSION

Our health care system would be far less affordable without new medicines—as demonstrated by purchasers embracing disease management as one of their leading cost containment strategies. In these programs, drug spending often increases while total health spending decreases. Weakening patents ultimately will increase health care costs, as the disincentive to innovate leads to fewer new medicines and, thus, foregone opportunities to cure or better manage costly diseases. As the Patent and Trademark Office (PTO) wrote in a July 30, 2002 letter to Senator Orrin Hatch, “This bill [S.812] would likely do the opposite of what its title [Greater Access to Affordable Pharmaceuticals] suggests—by limiting access to cutting-edge drugs, decreasing innovation, and ultimately harming the quality of treatments available to patients.”

Part of Hatch-Waxman's foundation is the protection of legitimate patent rights of pioneer companies. Without that protection, the research-based pharmaceutical industry will have reduced incentives to innovate and to create safe and effective cures and treatments of illnesses. Without that protection, the production of new drugs will suffer. Attacks on legitimate patent rights will lead to less consumer choice and less availability of new drugs, and will undermine the careful balance

of Hatch-Waxman between legitimate patent rights and getting generic drugs to market.

Thank you.

Mr. BILIRAKIS. Thank you very much, Dr. Glover. Dr. Levine.

STATEMENT OF SHARON LEVINE

Ms. LEVINE. Mr. Chairman, Congressman Brown, distinguished committee members, I am a pediatrician and Associate Executive Director of The Permanente Medical Group in the Kaiser Permanente Medical Care Program. I am testifying today on behalf of RxHealthValue, a broad coalition of more than 20 organizations nationally, consumer organizations, purchasers of drugs, providers, health benefit sponsors and health plans, including AARP, General Motors, AFL-CIO, United Auto Workers, DaimlerChrysler, Verizon, and Visteon. Collectively, RxHealthValue's members represent more than 100 million American consumers who have a great interest in the outcome of hearings such as this.

As a physician and as a member of RxHealthValue, my primary concern and the reason I am here today is the affordability of prescription drugs and the viability of prescription drug coverage. Reform of the laws covering generic availability is a key concern not only of this committee and of our coalition, but of American consumers, as was sharply reflected in the survey released last week by AARP. It is clear that there is strong consumer support for generic drugs and for the kind of reforms that would make generic drugs more accessible.

Congress has the ability to do any number of things to make prescription drugs more affordable. While reform of Hatch-Waxman is not the only step, it is an important step and presents an important opportunity to address a piece of what is going on that is making prescription drugs and prescription drug coverage increasingly unaffordable for American consumers.

Consumers, businesses, unions, the Federal Government, and health plans are aggressively attempting to manage staggering increases in prescription drug expenditures. Members of RxHealthValue spend billions of dollars each year on prescription drugs and have experienced anywhere from 17 to 20 percent annual increases for the last 5 years, threatening the viability of prescription drug coverage.

Our goal as a coalition and our goal as individual organizations is to provide value to our beneficiaries and to ensure that our members or patients get a dollar's worth of help at least for every dollar they spend on prescription drugs. Generic drugs are an important part of the value equation. As you know, they are subject to rigorous FDA review to ensure that they are as safe, as effective, as their brand-name counterparts; they have the same active ingredients, dosage forms, standards for purity, quality, and manufacturing, and the same clinical effect. The only substantive difference between generic drugs and their brand counterpart is the price.

The passage of Hatch-Waxman in 1984 was an important step in increasing the availability of generics. It established a regulatory framework to balance the incentives and the reward for continued innovation by research-based pharmaceutical companies with op-

portunities for consumers to actually benefit from those drugs based on market entry by generics.

RxHealthValue members are growing increasingly concerned, however, that the provisions of Hatch-Waxman have been inappropriately exploited to delay market entry and to delay access to high-quality, cost-effective generic drugs. Inappropriate Orange Book patent listings, repeated use of the automatic 30-month stay granted to the patent-holder has resulted in significant expense for consumers and unpredictable, unaffordable, and increasingly unmanageable pharmaceutical costs.

While it represents a very small percentage in terms of market share or in terms of the number of drugs, when we look at the expense associated with these drugs, it is quite large. General Motors testified that “evergreening” of the patents of five drugs, one each to treat ulcers, cholesterol, diabetes, allergies, and depression, increased its pharmaceutical costs by over \$142 million. In Kaiser Permanente these same drugs, the same five drugs, resulted in an expenditure of over \$120 million.

Just to give you some perspective, that \$120 million could have built and equipped a 100-bed hospital. This is a non-trivial expense even though it represents a small number of drugs.

Last-minute delays in generic availability make it difficult to plan and to budget for drug costs and to budget the appropriate resources. Our members have had to absorb unanticipated cost of hundreds of millions of dollars based on this small number of evergreening patents.

Delays in generic availability, though not the sole reason for the staggering increases in drug costs, certainly contribute and they result in efforts and activities by providers of health care coverage that have impacted consumers significantly.

Mr. BILIRAKIS. Please summarize, would you, please, Doctor?

Ms. LEVINE. Modifying benefits to reduce coverage, increase in cost-sharing, these have real impact on consumers, and the delay in the availability of quality generics contributes to this.

Our coalition recommends either eliminating the automatic 30-month stay, decreasing its length—and I would argue that the difference between 25½ and 30 months is substantive when we look at the expense related to these drugs—and if that is not possible, at least limiting it to one 30-month stay.

In addition, we support the fact that there ought to be regulation requiring the actual use of the 180-day exclusivity for generic drugs to actually result in a benefit to consumers and the generic actually coming to the market. Thank you very much.

[The prepared statement of Sharon Levine follows:]

PREPARED STATEMENT OF SHARON LEVINE, KAISER PERMANENTE MEDICAL CARE
PROGRAM ON BEHALF OF RXHEALTHVALUE

Chairman Bilirakis, Congressman Brown, and distinguished Committee members, I am Dr. Sharon Levine, a pediatrician and Associate Executive Director of The Permanente Medical Group, in the Kaiser Permanente Medical Care Program.

I am here today testifying on behalf of RxHealthValue, a broad and diverse coalition of more than 20 national organizations representing consumer organizations, purchasers of pharmaceuticals, health benefits sponsors and health plans including AARP, Families USA, Ford, General Motors, DaimlerChrysler, Verizon, Visteon Corporation, the United Auto Workers, the AFL-CIO, the Academy of Managed Care Pharmacy, the Alliance of Community Health Plans, the Blue Cross Blue Shield As-

sociation, and Kaiser Permanente. RxHealthValue is committed to research, education and both public- and private-sector solutions to assure that Americans receive the full health and economic value from their prescription drugs. It is an honor to appear before your Subcommittee to share our views regarding prescription drug spending growth and access to generic drugs and to underscore our belief that federal policy reforms are needed to restore balance in the pharmaceutical marketplace.

As a physician, my primary concern today is the affordability of prescription drugs and prescription drug benefits. Reform of the laws governing availability of generic drugs is a key objective of our coalition; it is also an important concern of American consumers surveyed in recent weeks by AARP who recognize the value that these drugs represent and who have shown strong support for reforms that would make generic drugs more accessible.

As the House Subcommittee with primary jurisdiction over prescription drug development, use and marketing, we want to particularly thank you for your leadership in holding this hearing. We also want to commend the Federal Trade Commission (FTC) and Chairman Muris for the extensive and thoughtful work the FTC has put into analyzing and addressing competitive concerns in the prescription drug marketplace over the past several years. It is our hope that today's hearing will continue the strong bipartisan effort to develop legislation to bring relief to consumers, as well as public and private purchasers of prescription drugs.

Congress could take any number of steps to make prescription drug more affordable. The step closest at hand is the one we are discussing today. We in RxHealthValue urge you to take action this session of Congress to make drugs that are more affordable more available.

THE PHARMACEUTICAL COST CHALLENGE

Consumers, businesses, unions, the federal government and health plans throughout the nation are aggressively attempting to manage soaring increases in prescription drug expenditures. Collectively, RxHealthValue's members represent more than 100 million Americans. The employer, insurer and consumer members of RxHealthValue spend billions of dollars each year on prescription drugs and report that year-to-year prescription drug spending is growing by as much as 20 percent, threatening the very viability of prescription drug coverage. Not surprisingly, a poll of Americans age 45 and over recently released by AARP indicated that there is growing concern among this group that rapidly rising prescription drugs costs are a threat not just to prescription drug coverage, but to all health care coverage.

The broad-based, diverse and respected organizations within RxHealthValue are growing increasingly concerned that the Hatch-Waxman law contains loopholes or provisions that have been exploited to allow the brand-name pharmaceutical industry to delay competition and access to high-quality, cost-effective generic drugs. We believe that inappropriate Orange Book patent listings and repeated use of the automatic 30-month stay granted to the patent holder has resulted in unpredictable, unaffordable and increasingly unmanageable pharmaceutical costs.

Kaiser Permanente is the largest private, non-profit health care system in the country, providing medical care to more than 8 million Americans. Permanente physicians prescribe and Kaiser pharmacists dispense more than \$3 billion a year in prescription drugs. Our physicians and pharmacists work very hard to deliver to our members the highest quality and most cost-effective pharmaceutical care possible based on the best available clinical evidence. Through this partnership, we are able to achieve significant economies in pharmaceutical care. Nevertheless, even our pharmaceutical costs continue to soar, growing at an annual rate of about 15 percent in recent years.

We expect pharmaceutical costs to increase significantly each year, frankly at rates that far exceed inflation. We recognize that prescription drugs can improve treatment, enhance the quality of life, and increase longevity. There are circumstances in which increased use of pharmaceuticals improves health and/or reduces spending for hospital or medical services. In these circumstances—for example, the use of lipid-lowering drugs to moderate coronary artery disease, or the use of SSRIs to treat depression—we work very hard to increase appropriate drug utilization, taking advantage of quality generics when available. Unfortunately, most increases in drug spending supplements rather than substitutes for other health care costs.

Generic drugs are important tools for managing rising pharmaceutical costs. Typically, generic drugs enter the market at prices reflecting a 30 percent discount over their brand-name counterparts. Within two years, the generic price may be as much as 60 to 70 percent less than the brand-name price.

As you know, generic drugs are subject to rigorous review by the Food and Drug Administration to ensure that they are as safe and effective as their brand-name counterparts. When compared to brand-name drugs, FDA-approved generic drugs have the:

- *Same* active ingredients,
- *Same* dosage form,
- *Same* standards for purity and quality,
- *Same* standards for manufacturing,
- *Same* amount of drug absorbed over the same time, and
- *Same* clinical effect.

The only real difference between generic drugs and their brand name counterparts is the price.

BARRIERS TO GENERIC COMPETITION

From our perspective, delays in the availability of generic drugs have lengthened in recent years and, if not addressed, will almost certainly force public and private purchasers to make difficult, painful benefit decisions that will almost certainly increase consumer out-of-pocket costs. The large companies that come to us for health care coverage tell the story: in an absolute sense, the ability of U.S. companies to compete effectively in the global marketplace without relief from rising prescription drug costs will be significantly diminished.

Last minute delays in generic availability make it very difficult to plan for future drug costs, a key concern for employer, health plan and governmental payers who need to budget the necessary resources in advance to pay for prescription drugs. By creating significant budgetary uncertainty, delays in generic availability force payers of all kinds “health plans, employers or state Medicaid programs—to seek ways to mitigate budgetary risk including modifying benefits to reduce coverage and in some cases increasing patient cost-sharing, both of which are opposed and resisted by employees, unions, and members of both public and private health plans. Such plan changes can lead to significant conflict among corporate purchasers, insurers, health plans and the people who depend on the health benefits they provide. The year-after-year double-digit drug cost increases make this problematic approach unavoidable. If the large increases in drug spending were in fact matched by reductions in hospital and medical spending, this would not be as significant a problem. But the promise of such an offset largely has proved illusory.

Mr. Chairman, over the last several years, as the patents of costly brand-name prescription drugs have approached expiration, purchasers have planned and budgeted for generic drug competition to reduce costs and increase enrollee choice. Such competition is critical to effective pharmaceutical benefit management programs as generic competition reduces costs by 60 to 70 percent. Time and again, however, purchasers have underestimated their liability, as brand-name pharmaceutical companies have been able to extend their drugs’ market exclusivity through repeated use of the automatic 30-month stay included in the Hatch-Waxman Act.

In addition, the brand-name pharmaceutical industry has successfully protected its older products from generic competition by listing unapproved and unmarketed uses or altering non-active ingredient components of the product in the Orange Book or through the U.S. Patent and Trademark Office.

For many of these product listings, however, independent experts have raised serious questions about whether such product changes really are true innovations meriting such protections. And when a brand-name pharmaceutical company contests a generic’s challenge of a questionable patent or exclusivity claim, the pharmaceutical company routinely is granted a 30-month market exclusivity extension, regardless of the merits of the case.

We are not aware of a single industry besides the brand-name pharmaceutical industry that has the ability to extend unilaterally and automatically protection against competition and believe that Congress never intended nor expected this provision to be repeatedly utilized for this purpose. We believe that the expiration of patents after their intended statutory term creates a strong incentive for companies to continue to develop innovative new products.

As a consequence of the practices of many in the brand-name pharmaceutical industry, Kaiser Permanente and other members of RxHealthValue have seen our prescription drug costs skyrocket. Since the enactment of Hatch-Waxman, the average number of patent extensions filed for “blockbuster” drugs has increased five-fold—from two to ten patents filed. And this trend has a very real and all-too-frequently devastating effect on the affordability of prescription drugs and ultimately all health care costs. Our concerns about inappropriate practices in the marketplace are not limited to the brand-name industry. We are troubled by and strongly opposed to

brand-to-brand and brand-to-generic settlements that are designed to delay market entry of generic competition.

There have been cases where generic pharmaceutical companies that initially filed a challenge to a brand-name patent and thus were eligible for the no-generic competition, 180-day exclusivity period reached an agreement with the brand-name company not to bring their generic drug to market. Such agreements, which can benefit both brand-name and generic companies handsomely, create no value for purchasers and consumers of prescription drugs.

I want to underscore our view that our support for restricting questionable practices that delay generic drug market entry does not mean that we oppose strong intellectual property protection. On the contrary, we fully appreciate the fact that without strong protection, the innovations that lead to breakthroughs for patients would not occur, nor would similarly important advances in other industries. At the same time, we do not believe that H.R. 5272 or H.R. 5311 would reduce intellectual property rights or threaten that principle that these rights are vital to a vibrant economy.

COST IMPACT ON RXHEALTH VALUE MEMBERS

Within the last several years RxHealth Value members have literally had to increase our budgets for pharmaceuticals by hundreds of millions of dollars a year. At Kaiser Permanente, a single manufacturer's efforts to "evergreen" just three of its drugs increased costs to our Program by over \$30 million despite the fact that we strive to avoid unnecessary costs whenever possible. General Motors, in earlier testimony before the Senate Health, Education, Labor, and Pension Committee reported that "evergreening" of the patents of five drugs designed to treat ulcers, cholesterol, diabetes, allergies and depression increased its pharmaceutical costs by over \$142 million.

Even more ominous is our fear that this trend will continue with increasingly negative impact. For example, without new legislation, GM estimates that if another five pharmaceutical "blockbuster" product patents that are currently scheduled to expire are extended, they will increase their prescription drug bill in excess of \$204 million during the period of delay of generic market entry.

Mr. Chairman, when access to lower cost generics is inappropriately delayed, consumers and other purchasers have no remedy or recourse—no way to recoup the excessive costs paid for pharmaceuticals. We are appearing before you to highlight the tremendous challenge confronting us and to seek legislative relief.

SUPPORT FOR BIPARTISAN HATCH-WAXMAN REFORMS

We believe that this is the time for Congress to intervene and pass legislation that will restore the balance between the value that accrues to consumers from competition and the benefits that accrue to brand-name manufacturers and consumers in return for innovation that was initially intended by Congress in the Hatch-Waxman Patent Restoration Act of 1984.

Consumers share the concerns of employers, insurers, and government purchasers regarding the implications of rising prescription drug costs. Consumers understand the need for policy interventions that would eliminate barriers to generic competition and are extremely accepting of generic drugs as an affordable, quality alternative to brand-name products.

Just last week, AARP released a landmark survey in conjunction with RxHealthValue that found older Americans:

- **Are concerned about the impact of rising drug costs on their health care coverage.** More than 9 in 10 Americans age 45 and older (92%) expressed concern about the impact of rising drug prices on the ability of insurance plans and employers to provide affordable health care coverage, including prescription drugs.
- **Frequently struggle to access needed prescription drugs without lower cost alternatives.** Nearly one in four (24%) of the survey respondents said that they were unable to afford a prescription drug medication when there was no generic available.
- **Believe that greater availability of generic drugs helps combat rising drug costs.** More than 8 in 10 (84%) of survey respondents strongly believe that making generic drugs more available is an important part of the solution to rapidly increasing drug prices. Moreover, 9 in 10 older Americans say they are willing to take generic drugs in order to reduce their drug costs.
- **Support legislation to make generic drugs more available.** Two-thirds of survey respondents (age 45+) support legislation to close loopholes used by some

pharmaceutical companies to prevent generic drugs from being made available to consumers.

We in RxHealthValue agree. If possible, Congress should eliminate the 30-month stay and transfer the 180-day generic exclusivity protection away from any generic company who has agreed to a settlement and award it to the next generic competitor who will enter the marketplace. If eliminating the 30-month stay altogether is not feasible, then Congress should enact legislation that provides for a single 30-month stay.

We greatly appreciate the leadership of Congresswoman Emerson and Congressman Thune and Congressmen Brown and Waxman, in raising this issue and developing thoughtful legislative solutions in the form of H.R. 55272 and H.R. 5311, respectively. We urge the Subcommittee to report out legislation and call on Congress to pass a bill before the session comes to a close.

Finally, I want to make clear that, speaking both for the physicians of Kaiser Permanente and the members of RxHealthValue, we are strongly committed to and supportive of pharmaceutical research and development. Kaiser Permanente itself conducts a great deal of pharmaceutical research. Pharmaceutical innovation requires patent protection to assure innovation. At the same time, excessive market exclusivity can be as great a deterrent to innovation as insufficient exclusivity. We fear that certain practices currently employed in the industry have effectively misdirected its attention away from true innovation and new product development and towards preservation of its revenue stream.

CONCLUSION

The intent of the Hatch-Waxman law was to achieve a balance between incentives to industry to stimulate innovation and patient access to the products of this innovation and affordable care. Over 18 years the balance has shifted as a result of questionable practices. But the law has not kept pace. It's time to restore the balance.

Mr. Chairman, we appreciate your leadership in holding this hearing. We look forward to working with you and providing any assistance possible in developing legislation in this area. I would be happy to answer any questions you may have.

RxHEALTHVALUE

RxHealthValue is a national coalition of large employers, consumer groups, labor unions, health plans, health care providers and pharmacy benefit managers that, through its members, represents more than 100 million Americans. RxHealthValue is committed to research, education and both public- and private-sector solutions to assure that Americans receive the full health and economic value from their prescription drugs.

PARTICIPATING ORGANIZATIONS

Blue Cross/Blue Shield; Kaiser Permanente; AARP; National Consumers League; Alliance of Community Health Plans; General Motors; Ford; DaimlerChrysler; Verizon; Families USA; Visteon; American Academy of Family Physicians; Academy of Managed Care Pharmacy; National Organization of Rare Disorders; International Union, UAW; AFSCME; Pacific Business Group on Health; Midwest Business Group on Health; Washington Business Group on Health; Advance-PCS; Caremark Rx; and AFL-CIO.

Mr. BILIRAKIS. Thank you, Doctor. Mr. Barondess. Did I pronounce that correctly? Okay, thank you. Please proceed.

STATEMENT OF MARK A. BARONDESS

Mr. BARONDESS. First of all, thank you, Mr. Chairman and Congressman Brown, for allowing me the opportunity to address this astute body today.

I am here today to discuss what I deem to be an extremely important issue in my life, and that is the entry of generic drugs into the marketplace prior to the expiration of lawful pharmaceutical patents. I thank you because this issue is directly about me, and it is about me and every other patient, and it is about me and most of your constituents. It affects all of us. I am not here today as a

lobbyist. I am not here as an advocate. I am here today solely as a patient.

I am greatly concerned as a patient about the potential harm that would come to the pharmaceutical research industry in the event there were any erosion of the patent protection that presently exists under existing law. I am really not interested today in entering into a political argument between the generics on one end of the table and me as a patient on the other end of the table, or what Kaiser Permanente wants or what Blue Cross/Blue Shield wants. I really don't care what they want. I care about what patients want and what constituents want.

In December 1999, if you would have asked me what was my most significant health problem, I probably would have told you male pattern baldness, and it is still a major problem for me. But, unfortunately, I discovered I had one other problem. In March of 2000, I heard the words for the first time, "multiple sclerosis." I had no idea what it was. I was upset. I was hurt.

I want to apologize to the committee in advance only because one of the manifestations of my disease is that my speech sometimes gets slurred and I go a little bit slower. Please understand that that is part of the problem, and I am not trying to delay or lengthen my speech for any other reason.

The best way I can describe MS to you is to imagine your own immune system attacking itself. Right now I have six lesions that are on my brain. When I first started with MS, I had three. My nerves are like frayed extension cords. You know what an extension cord looks like when it gets cut. It doesn't get the right signal. Well, sometimes my brain doesn't get the right signal; my legs don't get the right signal; my arms don't get the right signal, and it affects me.

Multiple sclerosis is a disease with no cure and with no known cause. While research from the pharmaceutical industry has yielded five, what have been called, I guess, these blockbuster-type drugs in the last 5 years, there is still no cure on the horizon. The best that I can hope for, the best that friends of mine that have MS can hope for, is that I stay out of a wheelchair. That is my daily goal, to hope that my condition does not progress any further.

Now on November 30, 2001, I did something that for me was somewhat extraordinary. I ended my career as a trial lawyer. I had been a trial lawyer for almost 20 years. During that 20-year period, I had the great honor of representing Members of this august body. I represented members of the Executive branch of government. I represented athletes, sports figures, Olympic gold medalists, celebrities, stars. I mean, you name it, I was very, very fortunate to represent them. Some of them, like Larry King or Montel Williams, I can still represent, but I can't go into court for them anymore. I am not allowed to do that because my multiple sclerosis has affected my ability to do my trial work.

Like the passion that each one of you have for your legislative goals and for your constituents and for your individual careers, I lost mine. It is kind of like if I was the captain of the Concorde, and all of a sudden I was told, "You can't fly anymore." My wings got taken away.

It is difficult for me to articulate to you the pain and frustration that I felt 1 day as I stood in a crowded courtroom in a hotly contested case and I passed out because a spinal tap that I had had the day before started leaking, and all the cerebral fluid from my little brain started to leak out my spine. It was a pain that I will never forget, and it is a pain that I still feel today.

But that is my disease. That is my MS. Although I look healthy, I am not healthy. MS is an invisible disease. Looking at me right now, I am sure that you cannot tell that I have no feeling on my left side, none at all. You could take a nail and put it in my left foot, and I wouldn't feel it. Last week at BWI Airport I was coming off the Park and Shuttle bus; I couldn't feel my left foot. So what did I do? I fell down the stairs of the bus.

Now a lot of people think lawyers have big egos. I like to think that I am not one of them, but I've got to tell you I was devastated. It was very embarrassing to fall down in front of a group of people and have people older than me rushing over, "Can I help you?" It is a humiliating experience.

Three weeks ago I went blind in my left eye. I don't know if any of you have ever lost your vision before, but I will tell you it is a scary thing to happen.

Almost every day I get seasick, but I don't go out on boats. It is all part of the disease.

Now why am I telling you each one of these stories? The reason I am telling you these stories is because, first of all, I want you to understand from a patient perspective; I could care less about PhRMA; I could care less about generics; I could care less about Kaiser Permanente. I care about what it means as a patient to be affected by disease in America. It doesn't matter that I have MS or if your mother has Alzheimer's or if Michael J. Fox has Parkinson's. We are all affected the very same way.

You do not know how it feels, and I hope to God that you never do know, what it feels like not to be able to play with your children because you are too tired. Imagine standing in a courtroom where you are examining a witness and, as you stand there, you totally forget what it is that you are asking the witness. It is a terrible thing to happen. That is the effect of the disease.

So why am I here? I am here to ask you to do the following:

I am asking you not to take any steps whatsoever that would in any way hinder the pharmaceutical industry in their development and innovation of drugs. It is too important.

We went through this whole thing—and I am skipping through all my comments because I realize I am running out of time. We went through this whole thing last year with Napster. I represent music artists; I know what Napster is about. Everybody was up in arms, "My God, we can't get our free music anymore. What's going to happen? We're going to protect the music. The music is important." Well, Elvis may be dead, but, I've got to tell you, his copyrights, they are alive and well. He is doing great.

We are in the same situation here, except you have something very unique. You have the power. You have the obligation, I would submit, to protect people like me, to protect your constituents, to protect your family, so that pharmaceutical innovation is not halted.

Generics do serve a good goal. They should continue to serve that goal. I am asking you to use your conscience, to use your compassion, and to exercise your best judgment in order that the pharmaceutical industry can continue to make breakthroughs to help people like me and to help people that are even less fortunate than me.

Thank you for your time.

[The prepared statement of Mark A. Barondess follows:]

PREPARED STATEMENT OF MARK A. BARONDESS, PATIENT

Chairman Bilirakis, Representative Brown, and Members of the Subcommittee, my name is Mark A. Barondess. I am an attorney who has given up my litigation practice because my diagnosis of multiple sclerosis precluded my ability to continue as a trial lawyer. I am here today because the subject of this hearing is one that is crucial to me and to many others like me who are affected by incurable diseases. The one belief all of us as patients have in common is that we continue to hope that some day, the word "incurable" will not apply to us. How this Subcommittee, and this Congress, treat the protection of intellectual property owned by research pharmaceutical companies has everything to do with whether or not our hopes will ever be realized.

As I am sure you know, Mr. Chairman, multiple sclerosis is a disease of the central nervous system that occurs in a minimum of 400,000-plus patients in North America. With the assistance of the Gallup organization, we are presently conducting a poll to hopefully gain a more accurate delineation of the actual number of MS sufferers. I believe the actual number may approach 3 million people. Multiple sclerosis can be a progressive disease, which causes a range of symptoms including loss of muscle strength in the arms and legs; compromised balance, coordination, and cognitive function; fatigue; blurred vision; pain; vertigo and bladder dysfunction. Its cause is not understood. MS generally is first diagnosed when a person is 20-40 years of age and its symptoms and progression are variable. MS can progress slowly or quickly, with an increase in symptoms or silently. The loss of physical and cognitive function may occur gradually over many years, or more dramatically over a shorter period of time. It can be difficult to predict the course of the disease in any given patient, so all of us are in a wait-and-see mode. We basically meet each day with the expectation that we will take it as it comes, and the hope that that day will be better than—or at least no worse than—the day before. And we always hope that this will be the day research will yield results that can be translated into a cure.

Today, MS patients have several therapies available to them, which palliate some of the symptoms and appear to slow the progression of the disease. The remarkable thing about that statement is that just 9 years ago, I could not have made it. Although patients have been affected by MS for many years, the first drug treatment that actually was targeted to this disease was not discovered and approved by the FDA until 1993. Since then, several other products have been approved that have provided incremental improvement. But no cure is on the horizon, and even the most optimistic experts in the field tell patients that nobody can predict when, or IF, there will be a cure. We know there is a great deal of research under way that could lead to greater understanding of this disease and even to a realization of how to cure it. But for that research to benefit patients, it must be translated into a real, tangible treatment. All of the basic research in the world put together does not benefit a single patient unless someone applies that research to bring it to the patient's bedside. And for patients who are waiting for a cure for MS, the people who will bring the research home to us are the research pharmaceutical companies.

With all due respect to the generic drug industry, Mr. Chairman, no generic drug company will ever take a basic research finding and turn it into a drug. The application of basic research in MS, through bench science, animal studies, and finally through human clinical trials will be accomplished by companies in the research pharmaceutical industry—the industry that some in Congress want to blindly characterize as evil, greedy, and uncaring. I don't agree with that characterization, Mr. Chairman, and I consider it to be offensive not just to the industry but also to every single patient in America who relies on the pharmaceutical industry for a viable treatment and for a cure.

It is astonishing to me that Congress has expended a massive effort to protect patents and copyrights on rock music, music videos and movies but seems quite eager to literally toss away protections for the industry that makes the most signifi-

cant difference in the lives of patients. I was stunned to learn about the recent Senate debate on legislation called the Greater Access to Affordable Pharmaceuticals Act. The debate seemed to be not at all about the pros and cons of the bill. In fact, there seemed to be an extremely poor understanding on the part of those who advocated this bill of what the legislation does or of the impact it would have. Instead, there seemed to be statement after statement about the cost of drugs and about various Senators' very negative views of the research pharmaceutical industry. It seemed to be statement after statement about insurance companies complaining about the cost of drugs. I found myself asking when the insurance industry suddenly had become the champion of the little person—the champion of the patient.

Mr. Chairman, as a patient whose disease requires a variety of treatments, I can tell you that insurance companies find very clever ways to reduce their costs, which mostly involve denying patients treatments they need. On September 30, 2002, I received a letter from Trigon Blue Cross/Blue Shield advising me that they would no longer reimburse me for a drug called Provigil, and innovative pharmaceutical product that helps me overcome the debilitating fatigue of MS. Why? Because the drug was originally designed to treat patients with narcolepsy, not MS. So now I am faced with the decision to pay \$1195 for 30 tablets, or just endure the fatigue. I am a victim of the insurance industry; by contrast, I am a beneficiary of the benefits of research-derived pharmaceuticals. To me, the truly sad thing about this debate was not what was said, but what was not discussed—patients who are waiting for new drugs that will cure their diseases. This so-called pro-consumer legislation didn't seem to be about consumers at all.

Mr. Chairman, the title of today's hearing indicates that is about pharmaceutical marketplace competition. And I think this is an important opportunity for all of us to be educated about this. But I want to urge you to look at this from another perspective—the perspective of whether Congress could take actions that threaten the availability of new drugs altogether. Speaking as a patient with MS, who is hoping and waiting for a cure, and as an attorney, I am telling you that this legislation WILL affect *whether* new drugs are available. I take this personally, Mr. Chairman, because what the Senate did, and what some in the House seem determined to do, will affect me personally. For me, this is not an academic exercise, and it is not a political prank; it is life in a wheelchair; it is life or death—mine.

Today, patent protection for pharmaceutical products is identical with that for all other patented inventions, except for one key matter. This is that software, microchips, automobile components, and video equipment have 20 years of protected life in the market because as soon as the invention is ready, and as soon as it is patented, it can go on the market. If potential competitors violate these patents, or appear to violate them, they can be prosecuted immediately; patent and invention are preserved. But drug products must be approved by FDA before they can go on the market. And to secure this approval requires years of research and human testing. So, for these products, the original patent may be issued many years before the product actually reaches the market. The so-called “effective” patent life is never 20 years and can be less than half that time. Provisions of the Hatch-Waxman Act were designed to restore some patent life to account for research time and FDA review time. But in no case does that extension ever come close to equaling the protections on high-technology developments in other areas.

Hatch-Waxman provisions also recognized that getting generic copies to market as soon as possible required actually allowing a generic company to infringe existing patents for the purpose of getting data needed for FDA approval. So, generic companies literally can start using the information in the patent the next morning. Unlike any other business, they don't have to wait until the patent expires to get their competitor product ready for market. The balance for this in Hatch-Waxman was to allow the patent holder a 30-month period to prosecute any potentially infringing patents, before a generic drug can be approved by the FDA. Remarkably, Hatch-Waxman also established a reward for the first generic company to infringe a patent, awarding that company 6 months of exclusive marketing.

So, to review the bidding, Mr. Chairman, here is what Hatch-Waxman did: (1) took away basic patent protections from drug companies by allowing generic copiers to use the patent information and make copies of the product beginning on the very day the patent is issued; (2) encouraged generic companies to infringe patents by rewarding the one who reached the patent infringement finish line first; (3) allowed a fraction of patent life to be restored for the time spent by a research company in conducting human studies and in waiting for FDA review to be completed; and (4) allowed a 30-month period for a drug patent holder to prosecute its infringed patents in court, before FDA can approve a generic copy.

So, we have essentially four components; two that benefit the generic company, and two that help the research company. In my book that's a balance. It might not

be a “one-for-one” trade, but it’s sure a flat see-saw. The Senate legislation and bills pending in the House tilts that see-saw precipitously, destroys the intended balance of the law, and threatens the future of research pharmaceuticals. It threatens my hope and well-being.

These bills go well beyond the recommendations of the Federal Trade Commission, an organization that I certainly believe is independent from the pharmaceutical industry. Even the FTC, in a report designed and executed in an effort to uncover flaws and abuses of the Hatch-Waxman law, does not say Congress should abrogate the fundamental patent rights of the research pharmaceutical industry. The Senate and House bills absolutely do that. In this report, certainly no “white wash,” the FTC unequivocally states that the Hatch-Waxman law has worked and has been literally responsible for the success of the generic drug industry. The FTC, after exhaustively digging for “abuses,” found fewer than 10 cases where there can be even the suggestion of going beyond the intentions of Hatch-Waxman; and these are not clear “abuses.” FTC does not paint a picture of an evil industry stomping out the benevolent intentions of a poor, struggling, philanthropic generic industry. Instead, FTC makes modest suggestions dealing with two of the rewards in the statute—the 30-months reward for the research company and the 6-months reward for the generic company.

Mr. Chairman, when you pass legislation—or even when you argue about it as fiercely and as maliciously as has been done in recent months—the effect will be a chill on pharmaceutical research, and that chill will—whether you want to admit it or not—affect patients like me. Will research in the pharmaceutical industry cease forever? Of course not. Will companies re-evaluate their research investments? Absolutely, unequivocally, yes. Patent protection is part of the calculus of research investment. Intellectual property is a mark of the value, the significance, and the quality of a research portfolio. Change the rules, and you will change those attributes of the system. Change the rules capriciously and you will have substituted politics for patients. I reject such a change.

Mr. Chairman, I am all for access to affordable drugs. I am all for appropriate transition from an older, branded drug product to a generic copy. I am all for the system working the way it was intended, and I am not against change. But I am against arbitrary change. I am against changing a system that is working because it makes a good sound bite in an election year. I am against attacking the research pharmaceutical industry in favor of the insurance industry.

Mr. Chairman, if you were to ask me what to do about pharmaceutical patent law, I would say strengthen it. Rather than weakening patent laws, I would urge you to enhance protections to provide greater incentives for companies to look for the cures that are deeply buried and very difficult to uncover. These are the kinds of cures for patients like me, whose diseases challenge even the most committed researchers. I would make the patent life of these products begin on the first day they are sold, not when the underlying molecules are created.

I am asking you to proceed with caution, and to make any changes on the basis of real—not fabricated—reasons. I am asking you to recognize that this law has worked by helping generic products get to market through a very abbreviated FDA review process that uses data gathered by a research drug company, allowing about \$1 million worth of development costs to substitute for about \$500+ million worth of research. I am asking you to recognize that the research pharmaceutical industry is one with huge risks as well as great rewards, and that those rewards accrue to people waiting for treatments and cures as well as to the companies who find them. And finally, Mr. Chairman, I beg you to approach this issue from the perspective of patients and to make your choices and your decisions based not on politics but on the needs of real people, suffering from real diseases for which there are no cures. Without your support, my dreams and those of my children may never become a reality.

Thank you.

Mr. BILIRAKIS. Thank you, Mr. Barondess, and we made you wait 5 hours to give your testimony, and we apologize for that.

People on the street often—that didn’t come out the right way, but, in any case, there have been concerns raised over the years I’ve heard of the efficacy, if you will, of generic drugs. We have even had a doctor, a member of this subcommittee, who questioned their efficacy in many cases, in other words, as related to the brand-name drug.

I would just ask very, very quickly, Dr. Levine, do you have an opinion on that, very briefly?

Ms. LEVINE. I do. The FDA has done an excellent job, and I think the situation in regards to generic drugs today is very different than it was when I started practice 25 years ago. The FDA has ensured that the quality, safety, and efficacy of generic drugs matches, and the bioavailability and clinical effectiveness matches, their brand counterparts.

Mr. BILIRAKIS. Okay. I think it is important, and I am going to ask Dr. Glover the same thing in a moment. But we have television here, and I think it is important for the American people to see that, so that they have a level of confidence.

Ms. LEVINE. I think the survey that I alluded to that AARP released a week ago actually was remarkable in that it showed how much American consumers actually have confidence in generics.

Mr. BILIRAKIS. All right, Dr. Glover, do you have any very brief opinion? Are you basically in agreement with Dr. Levine?

Mr. GLOVER. We certainly agree that the standards that FDA has established for their pool of generic drugs generally makes those drugs safe and effective. We do note, however, that there are circumstances in which the generic drugs are not, in fact, identical to the pioneer drug. In some circumstances for some patients those are relevant issues.

Mr. BILIRAKIS. Thank you. Well, Ms. Jaeger, how much does it cost the average generic manufacturer to produce a generic drug?

Ms. JAEGER. Actually, that is a very good question. I think it really would depend on actually the drug product. There are a lot of complex issues involving each and every drug product. So it can range from just shy of \$1 million all the way up to perhaps \$10 to \$12 million.

It really has to do with the scientific issues associated with that product, like with respect to conjugated estrogens. It also has to do with how many patents improperly listed or those that are deemed to be invalid that the generic company has to challenge. That all, basically, gets tied into how much it costs to bring a generic to market.

Mr. BILIRAKIS. As related, and you started, I guess, to get into it, as related to—well, in terms of the cost for development of the drug to conduct the bioequivalency studies, which are required by the FDA, which generally, as I understand it, doesn't really include that many people, how much of a cost? Would that cost be included in the dollar figure that you gave me?

Ms. JAEGER. Yes, it would. Again, that study will range depending upon the drug product.

Mr. BILIRAKIS. Dr. Glover, what would you say is the cost to the average brand-name manufacturer to produce a generic drug?

Mr. GLOVER. The number of recent studies shows that it costs about \$800 million to produce the drugs that actually get approved. That, of course, takes into account some of the failures for drugs that do not get to the approval process.

Mr. BILIRAKIS. Mr. Barondess, in your written testimony you stated that the reforms passed in the Senate would tilt, I think using your word there, would tilt the balance struck by Hatch-Wax-

man, thus, threatening innovation. Well, you have sort of addressed this, but I just wanted to give you a little more time.

What impact would the Senate legislation—maybe we can expand that into, and we have all indicated that there have to be changes made to the Hatch-Waxman and we have all indicated that we want to be a party to all that, but maybe we can add to that the other pieces of legislation, some that have been initiated here in the House. What impact would all that have on your hopes for a cure?

Mr. BARONDESS. It would have a devastating impact. I was fortunate enough this week to have a 45-minute meeting with Senator John McCain, and Senator McCain was very receptive and open to certain issues that he, I believe, had not considered in terms of the passage of the legislation in the Senate.

Generic drugs are great in terms of providing care for people, but generics are not innovative. Generics are not what you are going to look for to cure AIDS, to cure cancer, or anything else.

I would like to go just for a minute to the question that was asked of Ms. Jaeger in terms of cost. I would think that as the president of whatever it is, the generic group, that you would know the answer to the question. For instance, Fluoxetine, which would be the generic for Prozac, costs about 71 cents to make, but if you go to Wal-Mart you will pay \$63 for 30 pills that cost 71 cents. That is a generic markup of over 4,000 percent.

So when we are picking on the pharmaceutical industry, don't lose sight of where the generic companies are making money. Barr Lab's profits this past year are up 284 percent. Why is no one complaining about that? Why? Because it is good. They are providing a service. The generics should provide a service. But they are not creating any new medicine and they are no hope for me or anyone else to cure any disease.

Mr. BILIRAKIS. Thank you. Thank you, sir. My time has expired.

Mr. BROWN.

Mr. BROWN. Thank you.

Ms. Jaeger, Mr. Barondess I thought spoke eloquently about pharmaceutical innovation, and you have heard Mr. Glover and others say that S. 812 and other attempts to bring competition into the drug industry will destroy innovation. I also see huge numbers of dollars being spent on 600 lobbyists in PhRMA to protect things like this, not to mention huge amounts of litigation costs on 30-month and 6-month exclusivity, and all of that.

Explain why you think present law hurts innovation to come up with drugs that would help Mr. Barondess and why S. 812 could stimulate innovation.

Ms. JAEGER. Sure. I would be pleased to.

I think under today's system what is happening is this automatic 30-month stay, instead of giving the incentive for the brand companies to go back and do what we call true innovation, and bring novel medical products into the marketplace, instead this 30-month stay is giving some of these companies the incentive to go out and use what we call legal loophole innovation.

Now going out and getting patents and listing patents in this Orange Book that are improperly listed, I mean they don't cover the

brand products. They have nothing to do with the brand product. Yet, they are there just to block generic competition for 30 months.

What the Senate bill does is, basically, it is designed to curve this abuse and abuses that we see today in the system, as well as abuses tomorrow. Really what the whole bill will do is, basically, tell the brand companies: Go back and innovate, but stop misusing patents to block generic competition.

With respect to the example that was raised just a few minutes ago with respect to Prozac, that is a great example. There a generic company came in and challenged a patent. The patent was deemed invalid. It cost that particular generic company about \$10 million to take on that challenge. They were able to break down the patent, and the patent was deemed invalid. The product, their product came into the market almost 3 years earlier than it should have, saving about \$2.5 billion to consumers.

I also think it is important to note that we have members that innovate as well. We have a lot of members who innovate as well. One of our members is Teva. Teva is one of the leading generic manufacturers in the world as well as the United States. Teva basically brings a product into the marketplace called Copaxone that actually does treat MS.

All our companies want to bring innovative products. At the same time, they want to bring their generic products into the market. There should be a balance there.

So what we are asking right now is just saying there has been abuse. Clearly, like in the world of sports, you see an issue, like in basketball the 3 seconds rule, that is an issue. It is a problem in the game. You don't scrap the game; you just change the rule.

We are saying we all see the abuse here with respect to the 30-month stay. It is driving the companies to basically manipulate the system to extend their products. We are just asking for this to be changed so that we can bring our affordable medicines into the marketplace, so that consumers can actually afford their medicines and perhaps afford the miracle drugs as well.

Mr. BROWN. Dr. Glover, Hatch-Waxman allows the 6-month, 180-day exclusivity, as you know. I have talked to Waxman today and numerous times about this. Neither he nor the other authors 20 years ago envisioned where a name-brand would pay the generic that had the 6-month exclusivity, and the generic then would not go on the market for that 180 days, for all intents and purposes, giving an extra 6 months of exclusivity to the name-brand. I mean that is, obviously, what actually happens there.

Should that be permitted?

Mr. GLOVER. Sir, I would like to just explain that while we always expected that the 180-day exclusivity would give the generic the ability to be on the market without competition with other generics, the scenario that has arisen within the last several years that was the focus of some of the FTC issues is a circumstance whereby in the context of patent litigation the parties have decided to settle that litigation by virtue of having one party make payments in some cases to another party.

As the Chairman of the FTC said this afternoon, those settlements, even those involving payments, can be pro-competitive, competitive-neutral, or anti-competitive. The particular circumstance

that I believe you are concerned about is a circumstance whereby an agreement involving that first ANDA's 180-day exclusivity has an impact on subsequent generic applicants entering the marketplace beyond the ability of those subsequent applicants to affect the system themselves.

Mr. BROWN. If I can interrupt, it also means during that 6 months the price continues to be higher, rather than having the generic and compete it.

Mr. GLOVER. But that is generally not the principal concern of the FTC about those settlements. The principal concern was something that was brought about by a change in the law in 1998, whereby we changed the criteria under which the generic was eligible for the 180 exclusivity. The criteria had been, since 1984 until 1998 or so, that in order to get the 180 exclusivity, the generic had to successfully defend a suit, the patent infringement suit. Then they would get it.

The change in the law that was brought about by a court case was that, in order to get the 180-day exclusivity, all the generic had to do was be first. Only in that circumstance do you generate the particular problem that the FTC was most concerned about.

Mr. BILIRAKIS. The gentleman's time has expired. The gentleman from Illinois.

Mr. SHIMKUS. Shimkus, Shimkus.

Mr. BILIRAKIS. I knew that.

Mr. SHIMKUS. I don't serve on this subcommittee, but I appreciate the chairman, again, for having the hearing and allowing me to be a full partner in this debate.

We have got my little chart up there. Again, maybe you have had a chance to look at it over the break. Is this an accurate depiction? Why don't I just go, Ms. Jaeger, do you think this is an adequate depiction of what goes on?

Ms. JAEGER. Well, I think, actually—

Mr. SHIMKUS. And as short as possible.

Ms. JAEGER. Sure. I think actually what is relevant here is that, before 1984, the brand companies were enjoying about 8.1 years—

Mr. SHIMKUS. Is this an accurate depiction of what is going on right now? I don't want the history. I just want to know, is this what is going on currently?

Ms. JAEGER. Generally speaking, this is—

Mr. SHIMKUS. Thank you.

Ms. JAEGER. [continuing] yes, the trendline.

Mr. SHIMKUS. All right, Dr. Glover?

Mr. GLOVER. This is a representative example, yes, it is.

Mr. SHIMKUS. Great. And Dr. Levine?

Ms. LEVINE. I am not a patent attorney.

Mr. SHIMKUS. Okay. Either am I. I still ask these questions, though.

And Mr. Barondess—

Mr. BARONDESS. Yes.

Mr. SHIMKUS. [continuing] you are an attorney and a patient. Is that how you see this process? Obviously, you are pretty informed.

Mr. BARONDESS. Yes.

Mr. SHIMKUS. Now let me ask a question. On the bottom part it says, "Effective patent life," which is the time that looks like—and I know it fluctuates, but it is the time that the pharmaceutical company has those high prices to cover the research and development, is that correct?

Mr. BARONDESS. Correct.

Mr. SHIMKUS. Okay. Now I know that the intent of my friend, Mr. Waxman, when he helped craft this law was the 30-month extension was a tradeoff, as I understand—and here we can go to history—a tradeoff for the generics to file before the patent life expires. Is that a correct historical premise? That is what happened? Yes, Ms. Jaeger?

Ms. JAEGER. Yes. The generics are allowed to do the research and development during the patent time. In exchange, the brand companies are basically provided with 5 years of patent restoration in time. Therefore, the distortions on both sides of the equation were equalized.

Mr. GLOVER. I would have to disagree with that, if I may.

Mr. SHIMKUS. Sure, Doctor.

Mr. GLOVER. We need to recognize that while the first change that Ms. Jaeger reported on is accurate, namely, the Hatch-Waxman Act created an inability for the pioneer companies to enforce their patents during the time generics were doing their research and development, it is not the case that we were given 5 years of data exclusivity. Because the circumstance prior to the Hatch-Waxman Act is that our proprietary data, for which we pay substantial amounts of money and investment, was proprietary for a substantial period of time beyond 5 years.

The tradeoff for the generics being able to take advantage of our patents early in the process was that at the time they filed the generic drug application, it would have the opportunity to try to start at least litigation to resolve the patent issues before the generics got to market, and that is the 30-month stay.

Mr. SHIMKUS. Let me go on, and my time is short and I want to be respectful, but I do want to say to Mr. Barondess that Mr. Waxman and I and this committee and the floor, we have been pushing our orphan drug bill, which is an incentive to make sure that in the small populations that we continue to have research and development for a lot of diseases that are of small population size. So even though it might seem that we are contentious, there are things where this committee and Mr. Chairman, whom I respect, have been very, very successful.

If this chart is correct and the effective patent lifeline is at the bottom, and we have the Abbreviated New Drug Application line, and if that gets approved, it seems like it cuts into the effective patent life recovery time. If that is correct, Mr. Barondess, isn't that your concern?

Mr. BARONDESS. It is exactly the concern. You know, you try to look at these things and figure out what would be a simple solution to this. Just speaking as a public citizen, it would strike me that, instead of getting into 30 months here, 30 months there, and you have to file litigation in 45 days, and if you don't do this, you lose that right, wouldn't it be more simplistic if we just said, "Look, from the date that the FDA approves the drug that you get so

many years.”? That’s it. No extensions, no modifications, no anything. You just keep it nice and simple and clean. You avoid all this other.

I have heard a lot of discussion going back and forth concerning this 30-month period and everything else. Let me tell you, it is not the pharmaceutical companies that start the problem. It is the lawyers. You all have developed solutions for dealing with lawyers, and it is called Rule 11. So I would urge you to avoid any type of litigation-type solutions. Just make it simple.

Mr. SHIMKUS. And I will thank the chairman and really all the folks that have helped try to educate me before the hearing. I think this has been a good hearing. I appreciate the panelists. I think we have work to do. I will yield back.

Mr. BILIRAKIS. We certainly do have work to do. I thank the gentleman.

Mr. Pallone.

Mr. WAXMAN. What about me?

Mr. BILIRAKIS. I haven’t gone to you yet? That was not intentional. Mr. Waxman.

Mr. WAXMAN. Thank you, Mr. Chairman.

I thank all the witnesses for their testimony. Mr. Barondess—

Mr. BARONDESS. Yes, sir.

Mr. WAXMAN. —I, too, have a very close member of my family suffering from MS. I can assure you, not just for MS, but anybody suffering from any disease, we want to give the greatest incentive and encouragement for innovation and development of new drugs to fight these diseases.

Dr. Glover, I want to ask you a series of questions I think you can answer yes or no.

Does the Senate bill diminish the patent term restoration provisions of Hatch-Waxman?

Mr. GLOVER. In the context of, if I am not able to defend and enforcement my extended patent, it diminishes the value—

Mr. WAXMAN. Well, okay, but does it address the patent term restoration?

Mr. GLOVER. It does because it affects my ability to enforce my patents.

Mr. WAXMAN. Does it diminish the 5-year exclusivity granted each new chemical entity by the Hatch-Waxman Act?

Mr. GLOVER. I do not believe it addresses that.

Mr. WAXMAN. Does it diminish the 3-year exclusivity granted to each change in a new drug, such as a new dosage form?

Mr. GLOVER. Such as new dosage form, no.

Mr. WAXMAN. Does it diminish the 6-month exclusivity granted for pediatric testing of drugs?

Mr. GLOVER. It does not amend 505(a) of the—

Mr. WAXMAN. I would submit to you that we don’t want to, nor does this Senate bill, diminish any of the provisions we put in Hatch-Waxman to encourage innovation. The only provision that it diminishes is the 30-month stay. That 30-month stay was never intended as an incentive for innovation. It was put there to deal with the problem of generic companies who were in 1984 too small to be able to pay treble damages. At least that was the theory advanced to us. So we said we would have this 30-month stay.

But, Mr. Barondess, the lawyers did get into this whole thing. What happened is that the drug companies waited until 1998, and then they saw that they could use this 30-month stay to extend the period of time over which they would have a monopoly.

Now what happens is, when there is a monopoly, you can't have competition. Now my family member and you are very fortunate to have health insurance, but a lot of people don't. I know that MS drugs cost \$10,000 to \$12,000 a year. A person without health insurance is not going to be able to afford to pay it. If they had a generic version of these drugs, maybe, undoubtedly, the price would come down.

Dr. Levine, Dr. Glover has testified that the drugs examined in the FTC report constitute a tiny fraction of the drugs for which there is generic competition and provide no basis to conclude that there are no problems with the system.

Now the drugs identified by the FTC as having multiple 30-month stays based on late-issue patents were Platinol, Hytrin, Paxil, Taxol, BuSpar, two versions of Neurontin, and Tiazac. I may not be pronouncing all of them correctly, but, according to the FTC, these drugs have net sales ranging from \$100 million to over \$1 billion per year and combined sales of as much as \$5 billion per year. The FTC also found that obtaining multiple 30-month stays was a new phenomenon in the last 4 years with the potential to increase in the future.

Do you agree with Dr. Glover that the recent delays of generic competition on these eight drugs represents a trivial problem and not evidence of abuse?

Ms. LEVINE. Not at all. It represents a huge problem, not because of the number of drugs, but because of the cost associated with each drug.

The issue around access to prescription drugs, I can't support strongly enough Mr. Barondess' contention that we absolutely need to provide incentive and reward for true innovation. American consumers are willing to pay a premium today for innovation in the future. They are quite angry about paying a premium to reward clever legal maneuvering.

Mr. WAXMAN. I think that one of the best ways to get innovation is to make clear that at some point your monopoly will end, and once the monopoly ends, your pipeline of highest possible charges is going to come to an end as well. You are going to have to compete.

Therefore, you had better get new drugs on the market. You had better put your money into research and development of new products, not into lawyers to figure out how to play games with the law to keep the monopoly going as long as possible.

Now PhRMA says, if we enact this law, it would have a negligible effect on cost of drugs. Do you agree with that, Dr. Levine?

Ms. LEVINE. Not at all. I mean, I think I stated that for General Motors these five drugs, \$142 million. Kaiser Permanente is a not-for-profit organization. This money comes out of the pockets of our members and it comes out of the pockets of the purchasers and sponsors of health benefits who pay on their behalf. These are forgone wages.

Mr. WAXMAN. Let me ask Ms. Jaeger a question. Some people argue that if we eliminate the multiple 30-month stays, incentives for innovation will be undermined. That is the real issue.

Now to test this hypothesis, don't we need to know whether the patents that have triggered the successive 30-month stays, in fact, cover significant innovations? What kinds of innovations are covered by these patents?

Ms. JAEGER. I think it is a very good point. For the most part, the basic compound patents and the first-method-of-use patent, the patents that represent about 98 percent of the intellectual property rights on a brand product, are not involved in patent challenges. What are involved right now are the 2 percent of these patents that have to do with a container, computer methods, unapproved formulations, unapproved uses, kits. They have nothing to do with the brand product itself.

Mr. WAXMAN. So they can file a phoney patent that has nothing to do with the original drug, stop a competitor for 30 months, after all their patent time, plus all the time we restored to them and the exclusivity we granted them in addition runs out, and then they can still keep competitors off the market because they file a frivolous lawsuit based on a phoney patent?

Ms. JAEGER. That's absolutely correct.

Mr. NORWOOD [presiding]. Thank you very much, Mr. Waxman. Your time has now expired.

Ladies and gentlemen of the committee, I am going to play by the clock. I don't mind if we have rounds from now until midnight.

Mr. WAXMAN. Is this time coming out of your time?

Mr. NORWOOD. No, it is not. Since I am the chairman, Mr. Waxman, I can make an announcement.

We are going to stay on the clock. We will go around as long as any of you want to, but let's, please, when the red light comes on, it is over for that time period.

Mr. WAXMAN. Point of information: What if a witness is answering a question? You will allow them to—

Mr. NORWOOD. We will decide that as we face the facts.

Mr. WAXMAN. You are revising the rules under which this committee has always operated. The members have to complete their questions, but I don't think we ought to cutoff witnesses, if they have something to add to us that goes beyond the time.

Mr. NORWOOD. Thank you, Mr. Waxman, for your help.

Mr. Buyer, you now have 5 minutes.

Mr. BUYER. One of the things I am concerned about at the moment here, when Mr. Shimkus brought up this question about the 30-month stay, and I am glad Mr. Waxman is still on the committee so we can use him as a great resource, Mr. Waxman.

I am a little concerned here when you say, do away with the 30-month time period. Does that mean that we are to then go back to *LaRoche v. Bolar*? Are we to go back to that case and let that be the rule?

Ms. JAEGER. Mr. Chairman, can I answer?

Mr. BUYER. Well, you are the one that said do away with the 30-month.

Ms. JAEGER. Yes. No, we believe, again, that the offset for the research and development phase is the 5-year patent restoration

time. So, therefore, we don't believe we have to go back and look at the balance.

Mr. BUYER. You want it both ways?

Ms. JAEGER. Well, the——

Mr. BUYER. Wait a minute. You can't have it both ways, can you?

Ms. JAEGER. The 30-month stay, as Congressman Waxman indicated, was a safety net, and it was devised in 1984 to ensure that generic companies don't put a product into the marketplace that would infringe a patent. Since 1984, there hasn't been one generic product going into the marketplace that has infringed a patent. So the safety net is no longer needed. If anything, it is being exploited, to the detriment of consumers.

Mr. BUYER. Because the scientists are sophisticated enough to put into the marketplace an alternative compound or the bio-equivalent, am I getting this sort of right?

Ms. JAEGER. Generics are therapeutic equivalents.

Mr. BUYER. Pardon?

Ms. JAEGER. Generics are therapeutic equivalent to their brand counterpart, yes.

Mr. GLOVER. You are correct in suggesting that perhaps the reason that we have not had generic drug market entry in the face of valid patents is because of the 30-month stay, which gives a 30-month period of time during which the pioneer and the generic can begin to resolve the dispute over patent litigation. That substantially reduces the likelihood that a generic who receives final FDA approval would enter the market in a manner that is not responsible.

Mr. BUYER. Do you concur with this, Counsel, that we should do away with the 30-month?

Mr. GLOVER. We do not. We believe the 30-month is important, and contrary to assertions otherwise, it means nothing for us to have patents or patent term restoration if we do not have an effective way to enforce those patents. Where the patent infringement exemption has already limited our ability to enforce those patents, it is only appropriate that we be given the opportunity to try to enforce those patents before the generic has gotten final FDA approval.

Ms. JAEGER. May I respond?

Mr. BUYER. I am not going to be able to pronounce your name very well.

Mr. BARONDESS. Barondess.

Mr. BUYER. Sir, you are very articulate as a witness. I have been here 10 years, and your personal story is, in fact, very moving. I think that even though on this committee, when you leave here today, even though we may be of different parties and we have our different perspectives and we have our philosophies, I think all of us dream that if, in fact, it is ourselves or someone in our family who have some form of disease or an ailment, that we, in fact, want some form of an access.

We live in a great country, and that country makes these drugs available. Why? Because the great minds of the world all want to come to America because they can push the bounds of science.

Your plea to us was sincere and it was compassionate, and I just want to appreciate you. I think it takes bravery, it takes courage,

for you to be in a public forum and do so in such a personal manner. When you leave here today, I want you to be proud of yourself——

Mr. BARONDESS. Thank you.

Mr. BUYER. [continuing] because I think you have made a valued contribution to this legislation.

I yield back my time.

Mr. BARONDESS. Thank you.

Mr. NORWOOD. The gentleman yields. Mr. Pallone, you are now recognized for 5 minutes.

Mr. PALLONE. Thank you, Mr. Chairman. I am going to have to rush because I have to go to another meeting.

I just wanted to ask Dr. Glover a couple of questions. I have to say that, when I looked at your testimony, Dr. Glover, I was concerned because, you know, you say at one point that the findings of the FTC and the report do not support either the allegations of widespread abuse of Hatch-Waxman and patent law or the sweeping measures included in the legislation pending before Congress.

I have to say, I don't think there is any question, from looking at the report, that there is widespread abuse. I mean that is what it says. You've got all these groups, 78 Senators, Governors, AARP, FTC, you know even the Bush Administration's statement of administration policy, some of the Republicans like Mr. Thune all agree that there are abuses. Yet, you seem to say that there isn't really a widespread problem.

But then you go on to say that the FTC study focused on eight cases of concern to the Commission, and you sort of trivialize those, and you go through each one to say why it is not true. I have some information with regard to No. 3, which is the Wellbutrin. In your testimony you specifically claim that no challenge was ever brought against the patent on Wellbutrin. However, from what I understand, it is just completely false.

In fact, I have some documents here that I would like to submit to the committee that indicate that in June 1988 Teva, which was already mentioned, Teva Pharmaceuticals, filed a challenge to this patent. In addition, I have a copy of the stamp that shows it was sent by certified mail and received.

So why do you say in your testimony that no generic challenge was ever filed? Where does that come from?

Based on the documents, if I could, Mr. Chairman, if I could submit these documents to the committee——

Mr. NORWOOD. So ordered.

[The information referred to follows:]



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June 4, 1998

Douglas Sporn, Director
Office of Generic Drugs
Food and Drug Administration
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

ANDA # 75-310
BUPROPION HYDROCHLORIDE TABLETS, 75 mg and 100 mg
RECEIPT OF NOTICE UNDER SECTION 505(j)(2)(B)(i) AND 21 CFR 314.95

Dear Mr. Sporn:

In accord with 21 CFR 314.95 (e), TEVA Pharmaceuticals USA is hereby providing documentation of the receipt of all Notices of Certification for U.S. Patent Nos. 5,358,970, 4,507,323, 4,438,138, 4,435,449, 4,425,363, 4,393,078, and 4,347,257. The last of the two Notices sent to the affected patent owner, application holder, or authorized representative had been received on June 1, 1998. This date is evidenced by the attached copies of the return receipts. In accord with 314.95(f), the first day of the 45-day period provided for in section 505(j)(4)(B)(iii) of the Act is June 2, 1998, the first day after receipt of notice. The 45-day period will therefore end on July 16, 1998.

Sincerely,

DAJ/mca
Enclosure

cc: W. Fletcher ✓ D.J. ✓
C. Ben-Maimon ✓ E.L. ✓
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Sincerely,

Deborah A. Ismail
DAI/ma
Enclosure

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C. Bee-Masana ✓ E.L. ✓
P. Zwickson ✓
M. Goshko ✓
R. Kasan ✓

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Mr. PALLONE. Where are you getting this statement that the patents in question were never challenged by any generic? They were, in fact, challenged.

Mr. GLOVER. Congressman Pallone, I, obviously, would need to review the documents that you have in order to be able to respond fully, but I do believe that you are not challenging the statement that I did make, which is that there are multiple versions of Wellbutrin that are generic and that are currently on the market.

Mr. PALLONE. But you say, "The patents in question were never challenged by any generic." They clearly were.

Mr. GLOVER. Mr. Pallone, as I said, I've got to see your documents—

Mr. PALLONE. Well, I will be glad to give them to you. I don't know how that works.

Mr. GLOVER. It is not going to work now because your one page is not going to be sufficient for me to make a—

Mr. PALLONE. Okay, well, I would ask you to look at it. I will submit it for the record. I have asked you to look at it. I would ask you to respond, because the bottom line is they were challenged.

It makes me question to what extent your effort to try to refute these eight cases of concern to the Commission are accurate. I mean if the one isn't, I wonder whether the other seven are.

Mr. GLOVER. As I said, Congressman Pallone, whether that particular fact is accurate or not, it is still true, as I said, that contrary to concern that these patents were preventing generic versions of Wellbutrin from getting in the market, there are, in fact, several versions of Wellbutrin that are generic that are already in the market.

Mr. PALLONE. But are you denying, Dr. Glover, do you deny that there have been at least eight brand-name pharmaceutical products that have had greater than 30-month periods of market exclusivity, and that these are costing consumers, employers, and insurers, and states billions of dollars? You seem to be trivializing this and saying that this FTC report isn't really accurate. Are you saying it is not accurate; it doesn't show widespread abuse? That is what you say. I don't know how you can make that statement.

Mr. GLOVER. I stand by that position. The mere fact that patent protection prevents generic drugs from going on the market does not mean that there is abuse. Moreover, the view that the FTC studied the cases, that there are, indeed, patents that have resulted in 30-month stays that have been overlapping and non-current also does not indicate—

Mr. PALLONE. Well, what about the cost to consumers, the billions of dollars that consumers pay because generics don't come to market?

Mr. GLOVER. I understand. The mere fact that there is cost to consumers does not indicate abuse. We have patent protection for the particular purpose that the pioneers are able to recover some of the cost of R&D. That is to be expected.

Mr. PALLONE. So you don't think that excessive costs of that nature are something that we need to address?

Mr. GLOVER. I do not believe that the excessive cost indicates that there is abuse in the patent system. What the excessive cost might mean is that there is a greater need to have a more effective way for patients to access medicines, not that the pharmaceutical companies should be undermined in being able to enforce their patent rights.

Mr. PALLONE. I guess what I don't understand—and, again, I have to go—I just don't understand. We know that generics bring costs down. It seems to me that the whole purpose of this exercise by the FTC was to point out that, unfortunately, that is not happening as effectively as it should because generics aren't coming to market and we are not saving money.

So, I mean, for you to suggest that that is not significant in some way, I don't understand.

Mr. GLOVER. I do not believe the FTC took the position that, in the face of a valid patent, that there was anything inappropriate about a pioneer being able to enforce those patents, even if the effect of that was to prevent generic market entry.

Mr. NORWOOD. Thank you, Mr. Pallone. I will let you go over there a little, knowing you will be back.

The Chair now recognizes himself for 5 minutes.

Dr. Glover, the generic manufacturer can qualify for the 180 days of generic exclusivity by being the first generic to challenge a patented drug, and the generic now, since 1998, need not successfully defend this patent legislation. I would like for you to take a minute and explain to me, by eliminating this successful defense, what has that done to the landscape out there for brand-name drugs and generic drugs?

Mr. GLOVER. For perhaps brand-name drugs, it is a much more simple case. What it means is that the time on the market that the pioneer drug has between NDA approval and the first generic challenge has been trending toward a shorter period of time.

What we are finding is where the drug is what we call a new chemical entity, a molecule that had never been approved before, in that circumstance we are finding generic challenges about at 48 months, which is about as early as you can do it.

With products that are not of this new chemical entity class but are new uses for an old molecule, for example, where in those circumstances generics are able to file their applications at any time after new drug approval, we are finding that the time that those products enjoy on the market before a generic challenge is also shrinking.

The reason in part that those are shrinking is because there is an incentive for the generics, when they make a challenge to the patents, claiming that they are invalid or not infringed, the incentive for them to be first is quite strong; i.e., they get the 180-day exclusivity.

But because the rule for qualifying to be first has changed—namely, all you have to do is be first; you don't actually have to both be first, have a valid case, and successfully defend it—then you are going to have people who are going to file applications in circumstances where they know that they do not have a good challenge, and then try to enter an agreement that may prevent them from actually having to lose or they will file a case and then continue to modify what they intend to make; that is, continue to amend their generic drug application so that they can actually get it to the state that it should have been in at the time of the file.

Now the consequence of that is twofold. When the generic files its application early, it is quite likely that the generic is going to file its application before all of the patents that the pioneer has applied for have been issued by the Patent and Trademark Office and entered into the Orange Book. Accordingly, you enter a circumstance where the likelihood that the ANDA will be filed before all the patents have issued is increased, and that is exactly the circumstance that we have been observing, whereby you are getting an increase in so-called non-concurrent 30-month stays, because that is the particular circumstance that you need to have to happen for that to occur.

Mr. NORWOOD. Well, it is your opinion, or yours either, Ms. Jaeger, that the law actually should reverse the court finding and let's simply say that the successful defense is important for you to get the 180 days?

Ms. JAEGER. One, I would like to clarify the record that we don't believe that the dismissal of the successful defense really has anything to do with the increase in patent challenges. What we believe is the support for the increase in patent challenges is the fact that more and more patents are being listed in the Orange Book.

So you think about it; back in 1984, there were two drug patents that listed, and today we are looking at on average 10. So there is going to be more and more patent challenges, especially when you consider the fact that 98 percent, I said, of this intellectual property protection around a brand product has to do with a basic compound patent and first-method-of-use patent. The vast majority of challenges by a generic company have nothing to do with those patents. They have to do with the improperly listed patents in the Orange Book.

Mr. NORWOOD. You like it like it is?

Ms. JAEGER. We would be happy—actually, we endorse Senate bill 812, and we believe that successful defense is perhaps a very necessary element. We have no problem with it. We support it.

Mr. NORWOOD. Well, part of the reason I think we are having this hearing is you are probably not going to get that bill, and we need to work this out because there is right and wrong on both sides.

What happens in a generic company after you have the 180 days of the exclusive right? What happens to the price during that period of time? My understanding is that it isn't much different than the brand-name price during the 180 days.

Ms. JAEGER. That is true. I think we will just go back, since we have been using Prozac as an example, a generic company came in and challenged the validity of patent, and the patent fell for double patenting. There the challenge basically cost about \$10 million.

Mr. NORWOOD. So that really hurts the consumer that you have the 180 days?

Ms. JAEGER. Well, no, not necessarily, because if you think about it, during that 180 days in which the generic company gets to go into the marketplace, that generic product was basically about 20 to 30 percent less than the brand. The brand was at about \$2.60 a tablet before the generic went in.

Mr. NORWOOD. How much lower would it be if you didn't have the 180 days?

Ms. JAEGER. Actually, it is a very good question. It went down to 6 cents a tablet. So if you think about it, at 6 cents a tablet with 14 companies in there, there would be no way a company could take on a mega-challenge and spend \$10 million in breaking down a patent that provided \$2.5 billion in cost savings. So at 6 cents a tablet, there would be no way that these companies would go forward with patent challenges. They wouldn't have the resources, and the consumers wouldn't have the ability to have affordable medicine in a timely fashion.

Mr. NORWOOD. I noticed that my time is up. I would like to point out to my friend, Mr. Waxman, that I did let the witness finish.

Mr. Towns, you are now recognized for 5 minutes.

Mr. TOWNS. Thank you very much, Mr. Chairman.

Let me first thank all the witnesses for their testimony.

Let me begin with you, Dr. Glover. The former National Medical Association Dr. Lucy Perez has stated over and over that there is no such thing as one-size-fits-all drugs. Given that fact, shouldn't we be concerned about new medical discoveries and how changes to Hatch-Waxman may harm our ability to get access to the best drugs for the minority population, in particular?

Mr. GLOVER. Absolutely correct. What you have to be concerned about when you make any challenges to intellectual property protection for pharmaceutical companies is that you change their decisions about the types of risks they are willing to take, the types of investments they are willing to make. Where they are faced with the opportunity to make investments in small population products, whether it be orphan drugs or whether they be drugs for particular subgroups of the entire U.S. population, you have to be concerned that they will make their investment decision not to pursue those drugs because there are risks associated with trying to pursue targets that are often difficult to reach, at the same time knowing they are going to have a smaller market in which they can recover their cost. So, indeed, in those circumstances the drug companies may very well decide not to take those risks, to the harm and detriment of patients with the diseases that need to have very focused treatments.

Mr. TOWNS. I just want to follow up. Biologic products have provided some of the only cures for various neurologic diseases, actually, that disproportionately—let me put it this way—affect women, like MS and rheumatoid arthritis. What are some of the different investment constraints faced by this industry that we don't see with the regular pharmaceutical companies? Are there any?

Mr. GLOVER. They are substantial, but bear in mind that they are, of course, not part of the generic drug system. But they are substantial for the following reasons:

As a general matter, it is a substantially more difficult task to manufacture biologics products once you have found them, but the process of finding these products that affect the immune system, that have very subtle effects on biological systems that tend in many cases to be much more subtle than small molecule drugs, and knowing that the diseases that you are trying to affect will require you to have a long study time, those drugs are likely to be drugs that will have substantially greater costs associated with their development than some other products. Obviously, on a case-by-case basis you have to review that, but as a general matter these drugs tend to be a bit more challenging for the industry.

Mr. TOWNS. Right. Let me just throw this out to all the panel members. This way, I will be able to get my extra time.

I have to work this system here.

In your opinion, is cost the only concern we should have when it comes to the access to medication? Shouldn't we also be concerned about the right kind of medication for the patients?

Let me start with you, Ms. Jaeger.

Ms. JAEGER. Of course, we should be concerned with bringing new, innovative medicine into the marketplace. At the same time we also should be concerned about having affordable pharmaceuticals available for consumers. So it is, basically, we are looking

at products that are quality, that have the effect that you need, and that provide patients with good health care.

Here, sitting today, the issue before this committee is how to fix the abuses that have been identified by FTC and the industry and the others. I think the issue here that we are seeing that we clearly need to curb the abuse, but in no way does Senate bill 812 in any way touch the intellectual property rights as provided by title 35 for the brand industry.

So that this bill will not touch innovation and the generic industry, for the record, as amended. We will never support a piece of legislation that will have any chilling effect on innovation because we, too, realize it is a very critical component of our health care system.

Ms. LEVINE. I absolutely agree with you that cost is not the only issue that affects access, but cost is a serious issue. To invest in innovation without the knowledge that people can actually benefit from the products of those innovations is an illusory promise to the American people.

What is happening in the marketplace, what is a real-time issue today is that increasingly consumers are faced with shrinking coverage, shrinking drug benefits. This is a serious issue.

Dr. Glover is right; the cost of the biologics is enormous. Some of these therapies are \$20,000-\$30,000 a year. No individual is going to be able to access those biologics easily.

In order to ensure the viability of insurance coverage to cover these very expensive, high-value, high-health-value drugs, we have to absolutely ensure that we are getting a dollar's worth of health from other drugs.

Mr. BARONDESS. Just very quickly, because I think that this ties together everything that you are saying, do you remember there was a list over here of names, and it was everybody that was for the one bill? It listed Kaiser Permanente, General Motors, Blue Cross/Blue Shield, and then there was one name on the other side, and that was PhRMA, opposed.

Well, I just got a letter dated September 30, 2002 from Trigon, Blue Cross/Blue Shield. They were on the list. This is a letter where they are denying medication for my multiple sclerosis, and the reason that they are denying the medication is they are saying it is an off-label use, that there is not, as they put in their letter, that the therapeutic use of what this drug is is not supported by adequate evidence in clinical literature.

Yet, right here an article dated from February 2002, The Journal of Neurological Neurosurgery Psychiatry, underwritten by the Department of Statistics at Kaiser Permanente, says that this data suggests that 200 milligrams a day of this drug significantly improves fatigue and is well-tolerated in patients with MS.

Why is this important to me, Congressman? Because I was paying \$40 a month for this medicine under my health insurance. Now for 30 pills I have to pay \$1,195. I am not going to pay it. I am going to be tired, and I am going to be tired until every citizen has that medicine available to them. Just because I can afford it, I don't want to take it. I want to do everything that I can in my power to make sure that everybody else can get it at the same time that I can.

Mr. TOWNS. Thank you, Mr. Chairman. I yield back.

Mr. NORWOOD. Well, in our effort to allow all the witnesses to finish, Mr. Glover, you wanted to respond to the question?

Mr. GLOVER. As you are aware, we believe that the cost is not the only issue when we are talking about effective, efficient, and cost-effective health care in the United States. We believe that it is quite important that we have new and innovative medicines that decrease overall health care costs because they decrease hospitalizations, surgeries, emergency care, and things of that nature.

What is important, and principally important, in terms of health care costs is that you allow both for the innovation of these drugs and you allow people to have access to these drugs by having drug benefit programs.

Mr. TOWNS. Thank you very much, and thank you, Mr. Chairman, for your generosity.

Mr. NORWOOD. Thank you, Mr. Towns. Mr. Shadegg, you are now recognized for 5 minutes.

Mr. SHADEGG. Thank you, Mr. Chairman. I want to begin by congratulating my good friend, Mr. Towns, on the efficacy of his strategy. He got almost double the standard amount of time. Well done.

First of all, let me begin by thanking all of you. This is an extremely complex topic, and it is one where striking, I think, the right balance is very important, and it is a difficult balance to strike. I think each of you has brought important information to that effort.

Mr. Barondess, I want to thank you for what you are doing. I appreciate your efforts. I am particularly glad that Senator McCain gave you time to discuss those issues.

Dr. Glover, let me start with you. I am one who strongly believes that the capital has to be there for you to go find the drugs, the new, cutting-edge drugs that we all need. I appreciate very much that that really is at the edge of medicine right now, and it is improving health care for people in America and around the world.

Having said that, one cannot help but be concerned about the staggering increase in drug costs and the contribution of that increase to the cost of overall health care. Those numbers are in the neighborhood of 17 to 20 percent a year.

I want to ask you kind of a multiple question and let you kind of respond to it the way you would like. One, I hear from your testimony that you seem to think that you don't have a serious problem here. I would like, in that context, for you to tell me if you have some other idea on how we are going to deal with the increasing cost of drugs.

I would like you to also address what you believe the effect on your industry would be of codifying the FTC recommendations; that is, specifically, of limiting to one 30-month stay and of requiring that people file with the FTC an agreement between a generic and a pioneer drugmaker in the process of 180 days.

Mr. GLOVER. Okay. Bear in mind that our comments regarding whether there is a serious problem or not are addressed to whether there is a serious problem under the functioning of the Hatch-Waxman Act. Obviously, there are components to increasing health care costs that go beyond pharmaceuticals and go beyond the fact that we have patents.

Indeed, it is probably irrefutable that at some point the country will not be able to afford increases in health care costs.

Mr. SHADEGG. We are close to that.

Mr. GLOVER. We believe that we are more a solution to that problem rather than a problem in that scenario, in that we provide benefits by virtue of having innovative medicines that we believe reduce what would otherwise be the health care costs if we had not innovated drugs 10 or 20 years ago and we are not able to continue to innovate drugs for the next generation.

With respect to the effects on our industry of the proposals in S. 812, we need to start and be clear about the difference between what the FTC report recommends and what S. 812 does. The FTC report recommends a single 30-month stay, and they do that by saying that any patents or the only patents which are eligible for the 30-month stay are those patents which are in the Orange Book at the time the relevant ANDA is filed.

In contrast, S. 812 takes the position that any patent that is not in the Orange Book within the first 30 days after new drug approval is not going to be eligible for the 30-month stay. As I explained in my testimony, and probably more fully in my written testimony, the scenario whereby S. 812 cuts off the ability of patents to get the benefit of the 30-month stay 30 days up to the end of your approval does not have any basis in the way that companies really do their research and development.

Contrary to the perhaps implications but not actual statements of FDA earlier, where they were asked simply about the number of circumstances in which products were modified post-NDA approval and whether they got patents on those, the scenario that the pioneer industry wants to emphasize here is that there are often patents that are applied for before NDA approval that do not get issued by the Patent Office until more than 30 days after NDA approval. It is those patents that are often important innovations in the originally marketed product that need to get the protection of the 30-month stay. Those are things that would be cutoff by the provisions in S. 812.

With respect to the other provision which you asked about, which is the need to report to the FTC any settlements between pioneer and generic companies, while PhRMA has not taken a position on that, I would like for you to remember that Chairman Muris said earlier today that those settlements, even if they do get reported, can, indeed, be pro-competitive, competitive-neutral, or anti-competitive. Indeed, in those circumstances we do not believe that there should be a presumption that, because there is an agreement between a pioneer and a generic, that it is, in fact, hurting competition and preventing generic drugs from getting to the market.

Mr. SHADEGG. Ms. Jaeger, I would like to give you an opportunity to respond to the same question.

Ms. JAEGER. With respect to the Senate bill 812, it is really quite interesting that what we are asking for really is that all these patents that come after brand product approval, that they just be subject to the same standards that every other industrial sector actually abides by. So that if a patent truly represents innovation, a court is going to issue a preliminary injunction.

What is important to note, that in Senate bill 812 it actually reduces the standard, so there is a higher likelihood of actually a court issuing a preliminary injunction to the brand company against FDA approving a generic product. So it is very important to realize that we are not saying that they are not going to be able to assert their intellectual property rights. What we are saying is that this extra special protection, this 30-month stay, that has nothing to do with the merits of the patent, should not attach to those patents.

It is those patents that are the ones right now in our current system that are causing a lot of these consumer delays. So we are saying these patents, the ones that are inappropriately listed, should not get the automatic 30-month stay. They should have to stand or fall on the merits. That is why we believe that Senate bill 812 would solve this issue.

As to the listing issue that was raised earlier, the bill does have a provision in the bill whereby the brand companies do have to list their patents at the time of brand product approval plus 30 days. That is merely a codification of what we have today. Today, under the current statute, the brand company must file with FDA all patents they believe claim the brand product, and they do so today at the time of NDA approval. This will be no different.

The only difference is under current law there is no penalty provision for not listing. So what Senate bill 812 was designed to do was to stop the abuses of today as well as the abuses of tomorrow. So we want to ensure that all patents are basically put into the system and that way we could get affordable pharmaceuticals to the consumers in a timely fashion.

Mr. NORWOOD. Thank you, Mr. Shadegg. You did pretty well yourself.

Mr. Waxman, you are now recognized for 5 minutes.

Mr. WAXMAN. I just want to follow up on that last question. We have the Federal Trade Commission recommending only one 30-month stay. We have the witnesses from the Bush Administration saying they would like to limit it to only one 30-month stay.

Dr. Glover, is it PhRMA's position that you are against limiting it to one 30-month stay?

Mr. GLOVER. That is correct, Congressman.

Mr. WAXMAN. Mr. Barondess, you I think captured the frustration that you are feeling about a drug that you can't afford because your insurance company isn't willing to pay for it. What we want to do is achieve a balance. We want a balance that on one hand will encourage innovation and research and development of products that people are desperately looking for to help them with disease. On the other hand, we want lower-cost drugs.

So the balance we struck was that we give a patent to the monopoly, and at the end of the monopoly we want competition because that does lower the price of drugs. If we can't lower the price of drugs, if people don't have insurance, they can't afford it. But even insurance companies are refusing to pay because the costs are so incredibly high to them. So the shift is onto those who are insured. That is really the dilemma we have.

But I want to tell you a story because this Hatch-Waxman bill of 1984, I was around, obviously, when it was adopted. But I was

also around in Congress when we adopted a law called the Orphan Drug Act. We had people affected with diseases in so small numbers that the pharmaceutical companies didn't want to put money into developing drugs for them because they didn't see a high potential for profit.

So we held hearing after hearing after hearing. We didn't wait until the end of a session to hold the hearings. We held hearings, and then throughout that period of time worked out legislation to give the incentive for the pharmaceutical companies to develop these new drugs.

One of the incentives we gave them was an exclusivity over a product that they would develop for people with rare diseases because we will let them capture whatever profit there was and not have competition so that nobody will want to be involved.

Well, it turns out that MS is considered a rare disease for this purpose. When the companies were working on products for rare diseases, they had one drug called Avonex out there, and another company wanted to produce another drug that was pretty much like that.

Mr. BARONDESS. Betaseron?

Mr. WAXMAN. Not Betaseron but Rebif.

Mr. BARONDESS. Well, Rebif, Betaseron, and Avonex are all interferon-based drugs.

Mr. WAXMAN. So they wanted this other one, and the first manufacturer came in and said, "Well, they shouldn't be allowed to compete with us." So they held up the second drug for a very long time. I wrote to the FDA and I said, "Well, we wrote the law. We said that if there is an improvement in a second drug, we should allow it to be available." But the FDA took the most conservative position and refused to allow that second drug to go on the market. Well, that meant that the patients were being denied the benefit of another drug that would have helped them.

Now, again, the balance: We wanted to give the full incentive for the manufacture of a drug for a small patient population, but they took advantage of what we were trying to do to give an encouragement for one purpose and try to use it for their own profits. There is nothing wrong with that.

But when we see that when the laws are used by people for their own self-interest but contrary to what we ever envisioned when we adopted them, Congress has to act. I submit to all of the witnesses here that the Hatch-Waxman Act—we used to call it the Waxman-Hatch Act—never intended this 30-day period to be a way to stop a generic from coming on the market. We never thought that 180 days, which we adopted for an incentive for a generic to step up and compete, would be the basis for blocking any generic competition.

So it is time, I think, for us to revise this law, to revisit these issues. Those who have the benefit of the status quo never want to give it up, even if it is in the public interest.

I submit, Dr. Glover, I think PhRMA is taking a very appropriate position for its self-interest, but its self-interest is not, in my view, in this regard, to not change this law at all, consistent with, I think, the public interest of maintaining that balance of giving incentives for innovation and giving the benefit to the consumer at

the same time or at least at some time for competition and lower prices.

That is a balance I think Congress has to revisit. I hope that we can follow the example of the Senate, if not taking their exact bill, at least struggling with those issues and seeing if we can resolve them.

Thank you, Mr. Chairman.

Mr. NORWOOD. Thank you, Mr. Waxman. I will recognize myself now for 5 minutes and to follow up on that.

PhRMA may be taking a position that is in their best interest, but it may be in mine, too; it may be in yours, too. That is what makes us have this hearing. We are trying to understand that we don't do anything that interferes with innovation, which Mr. Baroness has pointed out is so important.

By the way, the insurance company that denied you the medication, was that an HMO?

Mr. BARONDESS. No, sir. I actually—

Mr. NORWOOD. That is good. I just wanted to know if it was or wasn't.

Let me follow up just a little bit, Dr. Glover, because you have stated that you are unhappy with simply one 30-month period in here. I would like for you to very carefully explain to the committee instances where a brand should be allowed to invoke multiple 30-month stays. Help me understand that.

Mr. GLOVER. Right. I think the easiest-to-understand circumstance is where in the development of a drug, after we have started the FDA approval process, that is, we are in phase 1, 2, or 3 trials, we do something to the drug that is important for its ability to be a marketable product. That is, we do something to reduce its side effects, to make it be delivered more efficiently, allow it to have more stability on the shelf so that it can actually be used and shipped in an appropriate way.

Mr. NORWOOD. That is at a time that it is already on the market?

Mr. GLOVER. No, this is at a time before it is on the market.

Mr. NORWOOD. Okay, you are still working on it?

Mr. GLOVER. Right. But when we make those innovations, we apply for the patent. We send the application into the Patent and Trademark Office.

Nevertheless, having made those innovations, we are still fairly far along in the process, and the drug gets approved before the patent gets issued by the Patent and Trademark Office. Indeed, it doesn't get issued by the Patent and Trademark Office until more than 30 days after new drug approval, but bear in mind it was a patent that was applied for beforehand.

In that circumstance, under the scenario that S. 812 would have, we wouldn't get the ability to have more than one 30-month stay. Now we take that circumstance and, as counsel is probably whispering into your ear, in order to get the multiple, non-concurrent 30-month stay, that patent has to be issued after the generic drug files this application.

Now in the circumstance of a 3-year data exclusivity period, that is, not non-new chemical entities, the generic can file their generic

drug application the day after the pioneer goes to market. So, obviously, this circumstance can happen.

In the case of a new chemical entity drug, this circumstance would have to have the patent delayed by the Patent Office for 4 years before it is actually issued by the Patent Office. The reason that is is because the generic applicant cannot file their application until 48 months after new drug approval.

So they file their application at 48 months. A new patent or the patent previously applied for gets issued by the Patent Office, and it goes into the Orange Book. They then end up with a non-concurrent 30-month stay.

Now then there is a much, much rarer circumstance, which is you have a product that is on the market, and although there was some exchange with FDA about this earlier, I am not sure it was clarified. There are several things that you can, in fact, do to a marketed product that would be innovations that are covered by patents, but that do not require you to get a supplemental NDA or a new NDA.

In those circumstances, the patent for that modification, which may be things such as shelf life, greater stability, and things of that nature, will be listed for the original NDA. So now you have a new patent that is getting listed after the original NDA approval. In those circumstances it is more likely in terms of timing that those patents might be issued by the Patent Office after the first generic files, and then, once again, you would have a non-concurrent 30-month stay.

We do not believe that the mere fact that some non-concurrent 30-month stays have been viewed by the FTC as being inappropriate or anti-competitive is a reason to prevent the possibility of a legitimate multiple 30-month stay from being available to pioneer companies.

Mr. NORWOOD. Are they right? Have any of them been inappropriate?

Mr. GLOVER. I would say that to the extent that they have been successful in challenging some of the multiple 30-month stays, they have done it under the antitrust laws, and, therefore, we do not believe we need to change the Hatch-Waxman Act to take care of those issues.

Mr. NORWOOD. So are you saying to me that perhaps this bill isn't the way, but maybe we need to look at that because there is an issue here?

Mr. GLOVER. I am certainly saying that this bill is not the way. It is our view that there are currently laws in place to take care of it. Indeed, on the particular issue that we are concerned about, which is that someone is actually knowingly filing a patent that should not be listed and knowingly bringing litigation on a patent that they know is invalid, the antitrust laws take care of that very clearly right now, and they are doing so in some circumstances that have been challenged by the Federal Trade Commission and the Department of Justice.

Mr. NORWOOD. Mr. Brown.

Mr. BROWN. I thank you, Mr. Chairman.

Dr. Glover, for the record, please provide a list of patents just discussed that have been issued after NDA approval, but that cover

the already-approved drug, and describe the innovation that the patent covered, if you would be willing to do that for us?

Mr. GLOVER. That is very difficult to find, sir. I am not sure I know about most of—

Mr. BROWN. I am sure that you and PhRMA's resources can put that together.

Mr. GLOVER. I cannot—first off, it is not within PhRMA's information; it is within the company's information, and I can't promise to do so. But to the extent that we can, we will try to be responsive.

Mr. BROWN. I appreciate that. PhRMA runs very coordinated efforts all kinds of ways with its member companies, and I am sure they will cooperate with you as well as they do in political campaigns. So I appreciate that.

Dr. Levine, my understanding is that employers in your coalition, which has been involved in some of this legislation, very much value and respect the protection of patents. I listened to you list the names of Verizon, a telecommunications company, and General Motors, and companies that live and die really on innovation and patents and intellectual property.

Do any of those members of your coalition believe that policies before the Congress in this area, that any of the legislation we are working on in any way undermines that interest?

Ms. LEVINE. The coalition members have agreed and have great concern about the issue of multiple 30-month extensions of patent. They also strongly support intellectual property protection.

One of the things that is challenging our members is the unpredictability, the inability to plan and to budget and to understand what the effective patent life is going to be, and when it is going to end.

Patents and intellectual property protection represent a legitimate return on the research and development efforts of innovative research-based pharmaceutical companies. No one argues with that.

The question is, how much return for how long and how predictable is it? Is the profitability of a company, of a research-based pharmaceutical company, to be driven from revenue based on clever lawyering to extend patents or should the rewards go to the company with the most innovative drugs?

I think our members have been frustrated by having to absorb enormous, unplanned, and unanticipated costs for drugs based on an expected expiration of patent, and then finding that the process of challenging the patent is leading them to have to manage what is essentially becoming unmanageable. The response to that is even more problematic both for the companies and for the beneficiaries they represent, because people are having to do things with drug coverage.

I absolutely agree with Dr. Glover that the issue is access. Ultimately, with a contraction of drug benefits, and we only have to look at what has happened to the Medicare+Choice Plans, look what has happened to the drug coverage available to seniors in Medicare+Choice Plans over the last number of years. The cost of prescription drugs, escalating at 17 to 20 percent a year, has resulted in significant decreases for Medicare+Choice members to

prescription drugs, which is why many of them joined those plans in the first place.

The mismatch between the revenues and the cost of prescription drugs has meant that many, many seniors now cannot afford the prescription drugs that they need, whether it is for an orphan drug for a rare condition or it is drugs for high blood pressure for which there is no generic available.

Mr. BROWN. Thank you, Dr. Levine.

Ms. Jaeger, you have heard Mr. Burr at the beginning with the FDA and the FTC here outline the number of ANDAs filed, the number of generics, the number of 30-month stays, on and on. It seems to me that this 30-month stay and 180-day exclusivity issue, while still in the course of 20 years, has been proportionately a very small number of drugs, obviously; that the number of drugs has increased, the number of times this has been done has increased as the years go by, as the companies, as the name-brands have seen the opportunities there and are driven by profit, as they should be, and are doing the right thing for their bottom line, and would not be very good companies if they weren't trying to take advantage of it.

We have also seen, obviously, the drugs they choose are those that have the highest dollar sales. Explain, if you would, and you have talked some about this, that the average number of patent filings for breakthrough drugs has increased fivefold, I think you and some others have said from two to ten since original Hatch-Waxman. Give us a couple of specifics there, if you would.

Ms. JAEGER. Sure. I think that I will stay with the example for Paxil. Again, as I was saying, back in 1984, Congress envisioned there would be two patents listed in the Orange Book that would be subject to this automatic 30-month stay, the basic compound patent, the first-method-of-use patent.

Since that time, especially in the mid-nineties, we started to see an increase, an incline in how many patents were being listed in the Orange Book per major blockbuster. Some were up into the twenties. On average, we are seeing ten. So these other eight, allegedly, protect the drug product.

But when we are looking at the particular drug product, they don't cover the brand product marketed. When you look at, as an example, Paxil, as I said, the basic compound patent, the first-method-of-use patent expired in 1992 and 1993, respectively. The next patent that was issued that was there at the brand product approval time was a patent for the hemi-hydrate form of the active ingredient. That, indeed, covered the brand product. That was appropriately listed.

If you were thinking if it was the only patent that was there, then from a competitor's standpoint generics could come in, and if they can design around that particular patent, they should be able to come to the market like every other industrial sector.

But, lo and behold, we have this automatic 30-month stay that kicks in. So even though they are going to be able to design around, theirs is kept off the market for an additional 30 months.

To complicate the matter, the company filed additional patents that went into the Orange Book for unapproved uses. There is complicated product-by-process patents and others. These patents we

do not believe should be listed in the Orange Book because they do not claim the drug product. These are the type of the patents that are actually causing more litigation, extending litigation, extending and making the litigation more protracted, so that we can't get resolution of an issue. So these are the type of things that we are seeing.

Senate bill 812 actually solves this issue because it would basically roll back the automatic 30-month stay. It would reduce the extra-special protection of this 30-month stay to only those patents that are listed at the time of brand product approval.

All other patents that come afterwards, again, would have the same intellectual property protection and rights as every other industrial sector and would be subject to a preliminary injunction standard.

So what we are seeing is a trend, and FTC's report actually said that right now we are seeing more and more patents listed. The more patents that are being listed, the longer the litigation, the longer the delay to the consumer.

What we are concerned about is that, when you think about it, we are hoping that in the future that the review times for generic applications should actually decrease. Then if we can get rid of some of these improperly listed patents, perhaps we can get immediate resolution or at least accelerated resolution as to a reasonable patent. So the product can go into the market in a timely fashion.

Mr. GLOVER. May I comment?

Mr. NORWOOD. Yes, you may. I am certainly going to abide by Mr. Waxman's wishes. Dr. Glover, I would like for you to comment. I would like to hear that.

Mr. GLOVER. Well, first, we need to go back to one of the earlier statements that Ms. Jaeger said. It cannot be stated accurately that the contemplation in 1984 was that there would only be two patents listed in the Orange Book. Indeed, there are three categories of patents that were deemed appropriate for listing, and of course you can have more than one member in each of those categories. Those were composition patents, formulation patents, and method-of-use patents.

Second, we need to also recognize that, as the number of patents per product that are getting listed in the Orange Book has increased over the years, it may have nothing to do with anything other than we are getting much more sophisticated in our science and our research and development.

We should also recognize that, regardless of the number of patents that are listed in the Orange Book, if they are all in the Orange Book at the time the ANDA applicant files its application, there will be a single, concurrently running 30-month period in which FDA cannot give final approval.

The last thing to note, though, is that the premise of the generic industry here and the proponents of S. 812 is that, if you get rid of the 30-month stay, that the generics will be able to get to market sooner. But as the FTC has already told us, the litigation, if there is litigation to the district court level, takes you at least 25½ months. If the generics intend to get to the market earlier, obviously, their intent is to go to market without having a resolution of the patent infringement matter and, therefore, taking the risk

that they are going to violate presumptively patents that belong to the pioneer.

Mr. NORWOOD. I would like to thank all of you. I know it has been a long afternoon, but it has been an important afternoon. This issue is very important to all of us, to Members of Congress and our constituents.

We are concerned about the increased cost in prescription drugs. I am also very interested in what that really means in net cost in terms of the lifesaving pharmaceuticals that are being produced and the cost savings that are being produced because of the efficiency of new drugs. None of us on this committee want to do anything with any law that interferes with new innovations in the marketplace that are saving so many lives and making so many people's lives worth living.

So thanks to all of you for your participation and thanks to the members.

We are now adjourned.

[Whereupon, at 4:20 p.m., the subcommittee adjourned subject to the call of the Chair.]

[Additional material submitted for the record follows:]

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF RETIRED PERSONS

Mr. Chairman and members of the Committee, on behalf of our organization and its 35 million members, thank you for convening this hearing. AARP strongly believes there must be better containment of prescription drug costs. Key to that is better access to generics, which we are working to achieve through education, litigation, and especially legislation that we urge you to enact.

Modern medicine increasingly relies on drug therapies, but the benefits of these drugs elude more Americans every day because of high costs that have reached crisis proportions. Spending for brand name drugs tripled in the last decade, rising from \$40.3 billion in 1990 to \$121.8 billion in 2000, and is expected to more than triple to \$414 billion in this decade. This is a tremendous problem for older and disabled Americans who rely so heavily on prescriptions. In fact, Americans age 65 and older make up only about 15 percent of the population but account for 40 percent of total prescription drug spending. And 75 percent of Americans age 45 and over use prescription drugs on a regular basis.

The failure of Congress to enact a Medicare prescription drug benefit this year has left our members disappointed—and more than ever in need of help in affording the drugs they rely on. That makes the need to improve access to generics all the more critical now.

Improving access to generic drugs is a safe and effective way to lower total drug costs. A survey we released last week found an overwhelming majority of Americans say generic drugs are an important part of controlling drug costs.¹ Indeed, switching from brand name to equally effective generic alternatives commonly saves consumers as much as 50 percent or more. Yet one in four of our survey respondents reported not being able to afford a prescription drug because no generic was available.

Americans are finding that they cannot get the generics they need because of loopholes in the law that allow brand-name manufacturers to keep these low-cost lifesavers off the market. Our survey shows that two thirds of Americans want Congress to close those loopholes now.

Legislation to close these loopholes was passed by the Senate in July by a wide bipartisan margin of 78-21. It would let brand-name drug companies receive only one 30-month patent extension per product, prevent brand-name companies from paying generic manufacturers to keep their products off the market, and allow generic companies to challenge brand-name patents for frivolous modifications like superficial changes in a drug's color or physical design. We strongly urge you and your

¹ The survey of 1,046 adults age 45 and above was conducted by ICR of Media, Pennsylvania and had a 3 percent margin of error for overall results. It was released by AARP along with two coalitions—Rx Health Value and the Coalition for a Competitive Pharmaceutical Market (CCPM)—on October 1, 2002

House colleagues to enact such a bill this year so that our members and all Americans can afford the drugs they so desperately need.

AARP SURVEY DETAILS

Because generics have so much potential to help curb skyrocketing drug costs, we went to the American people to learn what they think about these effective and affordable alternatives. We found Americans age 45 and above readily accept generic drugs as substitutes for brand names. For example:

- Ninety percent are willing to accept generic drugs as a way to reduce their drug costs.
- Two-thirds of Americans 45 and older already usually choose generics over brand names when available.

Americans also understand the importance of generics in addressing their growing concerns about drug prices.

- More than 90 percent are concerned—and 72 percent are very concerned—that high drug costs are making it more difficult for employers and health plans to provide affordable coverage.
- Eighty-four percent believe strongly that greater availability of generics would help combat increasing drug prices.

Of course, nine out of ten people surveyed said enacting a Medicare drug benefit this year is a priority. And, importantly, other research suggests that proper use of generic drugs in a Medicare prescription drug plan could save the program from \$50 to \$100 billion over 10 years.² Our survey also found that:

- Four out of five (81 percent) say it is important for Congress to enact legislation this year to make generics more available.
- And two thirds (67 percent) say closing patent loopholes that keep generics off the market is more important if Congress fails to enact a Medicare benefit.

Yet cynicism is high. The survey found that:

- Nearly three quarters (72 percent) of respondents say pharmaceutical companies exert too much power over Congress; only 11 percent disagree.
- And despite the brand-name manufacturers' mantra that their high prices are key to bringing new drugs to market, nearly three out of four (73 percent) respondents do not believe better access to generics will cause cuts in research and development.

Our survey results make clear that consumers, like so many public and private payers, are comfortable with and eager for generic alternatives to expensive brand-name drugs and unsustainable annual double-digit drug cost increases. Congress still has an opportunity this year to make drugs more affordable and end unfair industry practices.

We urge you to act now to close the loopholes that are keeping safe and effective generics off the market and costing consumers billions of dollars each year.

ADDITIONAL AARP EFFORTS

Legislation is just one of three prongs in AARP efforts to reduce prescription drug costs through wider access to and use of generics. We are also working to educate our members on the importance and value of generics. And we are working through the courts to challenge actions by brand-name manufacturers that keep generics off the market.

Education: On the education front, we are working to encourage our members to understand and use generics when appropriate, and to otherwise use drugs wisely, through the AARP "Check Up on Your Prescriptions" campaign. The campaign is designed to increase understanding of generics as alternatives to brand name drugs when appropriate, improve patient compliance with prescribed drug regimens, and reduce harmful drug interactions and overmedication. It includes national television and print ads, broadly distributed materials, and other joint efforts with the American Geriatrics Society, United Health Group, and the American Medical Women's Association. The messages are also being carried by AARP's own publications, *AARP Modern Maturity*, *My Generation* and the *AARP Bulletin*.

In addition to promoting generics, the AARP "Check Up" campaign is urging patients to tell their doctors about other medications they are taking. Currently about one third do not always do so, putting them at risk for adverse interactions. The campaign also encourages consumers to take drugs as prescribed. Skipping doses,

² Greater Use of Generics: A Prescription for Drug Cost Savings. Grant Ritter, Cindy Thomas, Stanley S. Wallack. Schneider Institute for Health Policy, Heller Graduate School, Brandeis University. Waltham, MA, 2001.

not filling prescriptions and unauthorized pill splitting are some of the measures consumers take in the wake of rising drug costs.

AARP research has found that 28 percent of consumers have stopped taking a drug before the prescription ran out and one in five have had a prescription in the past two years that they did not fill—usually because of the cost. Unfortunately, these misguided cost-saving measures can also prolong an illness or medical condition and increase the total cost of care.

Our prescription “check up” is simple to do. We are telling people to:

- Ask their doctor and pharmacist if there is a generic equivalent for brand name prescriptions.
- Make sure their doctor or pharmacist knows if they are taking more than one medication.
- Always take the right dose and full course of a prescription.
- And last, but not least, not let drug advertising talk them into believing they need a drug their doctor hasn’t prescribed.

These and other “Check Up on Your Prescriptions” tips can help bolster health and boost savings. More information about “Check Up on Your Prescriptions” can be found at the AARP Web place at www.aarp.org/wiseuse.

Litigation: The third prong of our efforts to increase use of generics is in the courts. AARP attorneys are serving as co-counsel, or have filed *amicus* briefs, in several cases charging brand-name companies with patent abuse, suppression of generic competition, and collusive agreements with generic manufacturers. The cases include:

- *In Re: Buspirone Antitrust Litigation*, a suit against Bristol-Myers Squibb Company (BMS) for alleged patent abuse related to a drug for anxiety. Just as BMS’ patent for the drug was about to expire, BMS brought patent infringement litigation against the generic competitors and thereby triggered an automatic 30-month stay of FDA’s approval of the generics.
- *In Re: K-Dur Antitrust*, a class action anti-trust suit alleging illegal agreements by three pharmaceutical companies that prevented the marketing of a low-cost generic alternative to a drug used to treat side effects of high blood pressure medications. K-Dur20 is manufactured by Schering-Plough Corporation and is one of the most frequently prescribed drugs to people over the age of 65. Schering-Plough paid \$75 million to two generic manufacturers in exchange for the promise to refrain from producing a lower-priced competitor.
- *In Re: Tamoxifen*, a class action against AstraZeneca Pharmaceuticals LP and Barr Laboratories, Inc., for an allegedly anti-competitive agreement involving one of the most widely prescribed breast cancer drugs. Barr abandoned a challenge to AstraZeneca’s patent and agreed to refrain from marketing a generic despite a federal district court ruling that AstraZeneca’s patent was unenforceable. In return, AstraZeneca agreed to pay Barr \$21 million and supply Tamoxifen to Barr for resale as a “generic” priced only five percent below the brand name version.
- *In Re: Cardizem CD*, antitrust litigation in which AARP argued that an agreement by Aventis Pharmaceutical, the maker of Cardizem, a high blood pressure medication, and Andrx, a generic manufacturer, to keep a generic off the market has harmed consumers.

AARP is involved in two other drug suits involving state efforts to contain costs.

- *In Pharmaceutical Research and Manufacturers of America (PhRMA) v. Michigan Department of Community Health*, AARP supports the state program to persuade prescription drug makers to offer rebates to lower the costs the state pays for its low-income residents.
- *In PhRMA v. Tommy G. Thompson*, AARP’s brief supports Maine’s Medicaid waiver demonstration project requiring drug makers to rebate a portion of the price of drugs purchased directly by individuals who are not otherwise covered by the state’s Medicaid program.

CONCLUSION

Improving access to generic drugs is key to controlling skyrocketing prescription drug costs and ensuring that older and disabled Americans have affordable access to the prescription drugs they need. Our survey results demonstrate that Americans are ready, willing, and eager to make the most of generic drugs. The survey also makes clear that the public is expecting Congress to act this year to close loopholes that keep generics off the market. Doing so is within reach this year. AARP urges you to enact such legislation.

FOOD MARKETING INSTITUTE
October 8, 2002

The Honorable MIKE BILIRAKIS
Chairman
House Energy and Commerce Health Subcommittee
2125 Rayburn House Office Building
Washington, D. C. 20515

DEAR MR. CHAIRMAN: The Food Marketing Institute (FMI), on behalf of our 2,300 supermarket and food wholesaler members, submits the following statement for the record in support of legislation (H.R. 5311 and H.R. 5272) that would provide consumers with greater access to affordable medications. In brief, these initiatives now before the House Energy and Commerce Health Subcommittee will bring modest but long overdue reforms to the Drug Price Competition and Patent Term Restoration Act of 1984 (P.L. 98-417) by closing loopholes in the Hatch-Waxman law that allows brand-name pharmaceutical companies to unfairly delay less expensive generic drugs from entering the marketplace.

As an industry that has approximately 3.5 million employees, our members are becoming increasingly concerned over the runaway costs for prescription drugs which are increasing by as much as 10 to 20 percent annually. If this disturbing trend continues unabated, it will undermine the ability of our members who are self-insured companies to provide their associates with health care coverage, and it may in fact force many supermarket companies to increase employee premiums, raise their co-payments or reduce benefits in order to offset these rising costs. In this regard, it is our firm belief that reform of Hatch-Waxman is needed now so that we can once again have a greater degree of balance and competition in the marketplace in terms of the availability and access to quality, cost effective generic drugs.

FMI's support for H.R. 5311 and H.R. 5272 is further predicated by the fact that many of our members have in-store pharmacy departments. We currently estimate that our supermarket members operate close to 12,000 pharmacy departments in the United States accounting for nearly 14 percent of the outpatient prescription drug market. Recognizing that rising drug costs adversely affects all consumers, especially seniors with limited incomes, the underinsured and the uninsured, we must make a concerted effort to increase the availability of more affordable generic drugs. It is simply wrong to allow brand-name pharmaceutical companies to unfairly extend their patent protection beyond the time allotted by Hatch-Waxman law. When Congress enacted this landmark statute, it granted extended patent protection for new brand-name medications for up to an additional five years to compensate pharmaceutical manufacturers for the time lost in obtaining market approval from the Food and Drug Administration (FDA). As part of that compromise, the Hatch-Waxman law provides for an expedited approval process for generic versions of post-1962 drugs.

Unfortunately, Congress never envisioned a system in which brand-name companies would file questionable last-minute patents which effectively blocks a generic equivalent from entering the marketplace.

This "gaming" of the system which has been occurring for the past five years must be corrected, and it is FMI's position that this can best be achieved by enactment of modest reforms as reflected in H.R. 5311 and H.R. 5272. Specifically, these initiatives would end needless delays associated with the automatic 30-month stay, accelerate generic drug introductions and would expedite resolutions of patent disputes. The Federal Trade Commission (FTC) has endorsed these reform to Hatch-Waxman, and the Congressional Budget Office (CBO) estimates that these changes to the 1984 law will save consumers and employers some \$60 billion over the next 10 years. Most importantly, reforming Hatch-Waxman would not discourage pharmaceutical companies from making future investments in the development of the next generation of innovative drugs.

To conclude, FMI appreciates the opportunity to submit this statement for the record in support of legislation (H.R. 5311 and H.R. 5272), and we look forward to working with the Chairman of Members of the Health Subcommittee on this important issue.

Sincerely,

JOHN J. MOTLEY III, *Senior Vice President*
Government and Public Affairs

cc: Members of the Health Subcommittee

RESPONSE FOR THE RECORD OF KATHLEEN JAEGER, PRESIDENT AND CEO, GENERIC
PHARMACEUTICAL CORPORATION

Question 1. Generic Drug manufacturers have said that you want drug patents to be treated just like other patents during patent litigation. That is, you argue that brands should not have a 30-month stay, but rather should have to argue for an injunction to prevent generic ANDA approval. Isn't it true, however, that the "Bolar Amendment" allows generic manufacturers to conduct what would otherwise be infringing activity prior to marketing? Why should drug patents be treated like all other patents during litigation, when they're treated differently when generic manufacturers are copying them prior to approval?

Response. The Generic Pharmaceutical Association (GPhA) agrees with President Bush's position that while brand name pharmaceutical manufacturers "deserve the fair rewards of [their] research and development, [they] do not have the right to keep generic drugs off the market for frivolous reasons." We believe that the 30-month stay provisions of Hatch-Waxman are increasingly manipulated by some brand companies to delay the timely introduction of more affordable generic products. We believe that several measures are necessary to ensure timely resolution of patent disputes and restore predictability to the system.

When a generic applicant challenges a patent and the brand company sues the generic for patent infringement, the generic drug cannot be approved for 30 months (unless they win the lawsuit). This "30-month stay" that automatically delays generic approval is unique in the patent litigation world and is awarded to the brand company regardless of the merits of their case. The Greater Access to Affordable Pharmaceuticals Act (GAAP) passed by the Senate in July would limit brand companies to a single 30-month stay for the patents that are listed in the Orange Book at the timer of brand product approval.

The FTC study, issued in July 2002 during the Senate debate on GAAP, found that "[f]rom 1992 to 2000, brand-name companies have listed patents in the Orange Book after ANDA has been filed for the drug product in 8 instances; 6 of these 8 instances occurred since 1998. For the 8 drug products, the additional delay of FDA approval caused by the additional 30-month stays (beyond the first 30-month stay) ranged from 4 to 40 months. In all 4 of the cases so far with a court decision on the validity or infringement of a later-issued patent, the patent has been found either invalid or not infringed by the ANDA." (*July 2002 Generic Drug Entry Prior to Patent Expiration: An FTC Study*)

The study went on to note, "[i]n the future, patent infringement litigation brought by brand-name companies against generic applicants that have filed ANDAs with paragraph IV certifications may take longer to resolve. The data suggests that cases involving multiple patents take longer than those involving fewer patents. As for June 1, 2002, for 6 out of 7 cases that have been pending for more than 30 months before a decision from a district court, the brand-name company has alleged infringement of 3 or more patents." (*July 2002 Generic Drug Entry Prior to Patent Expiration: An FTC Study*)

Let's look at an example of the abuses that result from multiple 30-month stays. The well-known anti-depressant Paxil, which has annual sales of \$2 billion, is a good example of a drug that has benefited from the GlaxoSmithKline's ability to get multiple 30-month stays and stack patents in a successful effort to delay generic competition and consumer savings.

The original patents covering Paxil expired in the 1990s. GlaxoSmithKline was able to obtain a patent claiming a particular crystalline form of the drug. This patent expires in 2006. Generic companies have sought to bring a version of Paxil to market that does not infringe on this patent.

In 1998, several generic companies filed applications to bring a generic version of Paxil to market, claiming they did not infringe the still unexpired patent listed in the Orange Book. At the time the generics filed, GlaxoSmithKline sued, triggering a 30-month stay.

Since 1998, GlaxoSmithKline has been able to obtain nine new patents and list them in the Orange Book. Some of these patents are for minor modifications of the active ingredient, different formulations, and unapproved uses. These patents do not even claim the product that is currently being sold, yet they are listed in the Orange Book.

As a result of these patents, GlaxoSmithKline sued the first generic company four additional times, resulting in five additional 30-month stays. The last stay will expire in November 2003. If these patents are upheld in court, a more affordable generic will not be approved until 2016.

Thus, through patent “stacking,” even after the original patents on Paxil expired, GlaxoSmithKline was successful in getting four additional 30-month stays, and may delay the introduction of generics for more than a decade.

The 30-month stay provisions of GAAP make important process changes that will lead to a more predictable, rational pharmaceutical marketplace. GAAP limits brand companies to a single 30-month stay for patents listed at the time of brand product approval. This eliminates the brand companies’ ability to get multiple 30-month stays from generic competition by listing new patents.

Taken as a whole, the 30-month stay provisions of GAAP along with other provisions in the legislation, will ensure timely resolution of patent disputes and prevent end-run tactics that delay competition.

With regard to the Bolar Amendment, this provision provides a mechanism by which generic companies may begin research and development, and other activities necessary for FDA approval of a generic drug product prior to the expiration of a patent on a brand-name product. The Bolar Amendment specifically provides that such activities “shall not be an act of patent infringement.”

In *Eli Lilly & Co. v. Medtronic, Inc.* (496 U.S. 661 (1990)), the Supreme Court, in an opinion by Justice Scalia, found that the Bolar Amendment was intended to work in tandem with the patent term restoration provisions of Hatch-Waxman to respond to “two unintended distortions” in the patent law. The patent term restoration provisions address the fact that a patent holder cannot profit prior to obtaining FDA marketing approval. Likewise, the Bolar Amendment assures that the patent holders do not enjoy a de facto patent term extension during the period after expiration but prior to marketing approval for a generic product. Thus the patent term restoration provisions and the Bolar Amendment are complementary mechanisms intended to achieve a balance in the law.

Question 2. S. 812, as passed by the Senate, restricts brand manufacturers right to sue if patent litigation is not initiated within 45 days. Besides pharmaceutical patents, what other industry patents should become unenforceable if not sued upon within 45 days?

Response. The issues with the 45-day “statute of limitations” are closely linked to the issues of appropriate patent listing and stacking multiple patents.

Several interlocking provisions stop the abuse of the 30-month stay provision. One of them is creating a 45-day window for listing patents. Currently brand manufacturers lists patents within 45 days of the generic filing because they know they can get an automatic 30-month stay on each patent. Once the 30-month stay loophole is removed, the incentive to list patents in a timely fashion, or at all, may be eliminated.

The generic pharmaceutical industry proposed the 45-day window provision as a compromise that prevents brand companies from circumventing a new potential loophole created by the single 30-month stay provisions of GAAP. It requires the brand companies assert their intellectual property rights during the 45-day window that starts any patent challenge. This “statute of limitations” (which was merely borrowed from other industrial sectors) concept ensures that brand companies plays on a level playing field.

Question 3. How much does it cost the average generic manufacturer to produce a generic drug? You state in your testimony that brand drugs exceed generic drug costs by a factor of ten. To be fair, it also costs roughly \$600-800 million to develop a brand drug. How much does it cost a generic manufacturer to develop its drug and conduct bioequivalency studies?

Response. The issue of pharmaceutical research and development is used repeatedly by the brand pharmaceutical industry to suggest that eliminating barriers to a competitive market will somehow harm the introduction of new medicines. GPhA disagrees with this premise. It is our position that the current system harms innovation by rewarding patent creation rather than the discovery of medicines. Further, we believe that the current system encourages litigation instead of research and development. The proposals we seek if implemented would refocus the brand industry on true R&D rather than on legal loophole innovation.

Based on our experience, the cost for the development of a generic drug can range anywhere from \$250,000 to tens of millions of dollars. Generic drugs may take anywhere from 1-10 years to develop.

In 1998, the Congressional Budget Office (CBO) published an analysis of the contributions of generic medicines to consumers since 1984. The CBO study concluded that the savings to consumers generated by a vibrant generic pharmaceutical industry is enormous. “CBO estimates that in 1994, purchasers saved a total of \$8 to \$10 billion on prescriptions at retail pharmacies by substituting generic drugs for their brand-name counterparts.”

The study also found that generic competition has been good for innovation within America's brand pharmaceutical industry. "Between 1983 and 1995, investment in R&D, as a percentage of pharmaceutical sales by brand name drug companies, increased 14.7 percent to 19.4 percent. Over the same period, U.S. pharmaceutical sales by those companies rose from \$17 billion to \$57 billion. Overall, then, the changes that have occurred since 1984 (the Hatch-Waxman Act) appear to be favoring investment in drug development."

One additional fact is worth noting in response to the brand pharmaceutical industry's continued insistence that leveling the competitive playing field will hurt innovation: the statistics on brand company investment in innovation versus its investment in marketing. From 1997 to 2000, drug maker spending on consumer advertising more than doubled. At the same time as billions were being spent to sell expensive brand pharmaceutical products to the public, research employment dropped by nearly 2%, while marketing employment increased by 58%. An industry analysis by Boston University experts showed that brand pharmaceutical companies employ 81% more people in marketing than in research.

According to the latest available data, the total prescription drug expenditure in 2001 was \$172 billion, or approximately \$601 per person. That represents an increase of 17% over the previous year. Of that total, approximately \$13 billion, or approximately \$48 per person, was spent on generic pharmaceuticals.

As a result, the amount of money invested by generic pharmaceutical manufacturers, on the basis of sheer dollars, pales by comparison. However, if you compare R&D investment for brand and generic companies on the basis of a percent of gross profit, the leading generic companies and the leading brand companies' average 15-17% of gross profits invested in research and development. We believe that this statistic demonstrates that the commitment to product development is as strong in the generic industry as it is for our larger brand pharmaceutical counterparts.

Question 4. You speak of the intent of Hatch-Waxman in your testimony. Do you honestly believe that the authors of Hatch-Waxman intended for the first generic to challenge a patent to qualify for the 180-day exclusivity, regardless of whether or not they're sued?

Response. Clearly, the framers of Hatch-Waxman, who included Congress, experts, and members of both the brand and generic industries, understood that the 180-day exclusivity period is a powerful incentive for generic companies to bring patent challenges. And this process works well in removing barriers that have prevented consumer access to affordable generic medicines.

When the Hatch-Waxman Act was enacted in 1984, it included a provision that created a process by which generic pharmaceutical companies could challenge patents on brand name pharmaceuticals that they believed unfairly delayed generic competition and consumer savings.

Under the Hatch-Waxman Act, brand companies "list" the patents with the FDA that claim their drug. When a generic manufacturer files an application with the FDA, it must tell the FDA whether it is challenging any of the patents listed by the brand. If so, the brand company is given 45 days to sue the generic for patent infringement. This results in a court case that allows the generic company to attempt to invalidate patents preventing competition. With the average cost of a patent challenge estimated at \$10 million for the generic company, and requiring a multi-year development and legal commitment, the 180-day exclusivity provision provides a powerful incentive.

It is important to note that if a generic company successfully challenges a patent, then the intent of the Hatch-Waxman framers has been effectuated. The 180-day exclusivity award is a critical aspect of that intent.

Clearly, the impact of this incentive has been positive for consumers. Over the past several years, a total of 12 patent challenges have created more than \$27 billion in savings for consumers. These patent challenges include:

- Prozac: 2.5 Years early at a cost savings of \$2.5 Billion
- Buspar: 17 Years early at a cost savings of \$8.8 Billion
- Terazosin: 13 Years early at a cost savings of \$4.6 Billion
- Taxol: 11 Years early at a cost savings of \$3.5 Billion
- Zantac: 4 Years early at a cost savings of \$2.45 Billion
- Procardia: 8 Years early at a cost savings of \$2.4 Billion
- Plantinol: 11 Years early at a cost savings of \$1.0 Billion
- Ticlid: 3½ Years early at a cost savings of \$492 Million
- Lodine: 7 Years early at a cost savings of \$414 Million
- Relafen: 2 Years early at a cost savings of \$413 Million
- Climara: 7 years early at a cost savings of \$378 million

But even this component of Hatch-Waxman would benefit from reforms included in the GAAP legislation.

The current law grants 180 days of exclusive generic marketing to the first generic company to successfully challenge a brand drug patent. However, recent court decisions have reduced much of the 180-day exclusivity's incentive value by triggering the exclusive marketing period on a successful trial court decision. As a result, the 180-day period expires before the appeal can be heard. The bill fixes this by moving the triggering event out to the date of an appeal decision.

The current law does not adequately address situations where the first generic challenger does not, or cannot go to market after the resolution of the lawsuit. GAAP addresses this problem by providing for the forfeiture of the first challenger's exclusive marketing period if they do not go to market within 60 days of specified events.

In sum, Hatch-Waxman recognized that brand companies need and deserve a period of market exclusivity to recoup their investment in research and development. It established a specific period of exclusivity, and then permitted the date-certain introduction of more affordable generic versions of these brand drugs. But no generic drug can be approved, or enter the market as long as a patent protects the brand product. GAAP does not change this fact. Rather, it ensures that patents expire when Congress intended. It closes loopholes that in essence create an indefinite period of exclusivity. It ensures that patents come to an end, and that generic products can enter the market when the patents expire.

The legislative proposals supported by GPhA benefit both the brand and generic segments of the pharmaceutical industry, as well as the American consumer, by restoring predictability to the marketplace.

FEDERAL TRADE COMMISSION
WASHINGTON, DC
November 22, 2002

The HONORABLE MICHAEL BILIRAKIS
Chairman
Subcommittee on Health
Committee on Energy and Commerce
United States House of Representatives
Washington, D.C. 20515

DEAR CHAIRMAN BILIRAKIS: I very much appreciated the opportunity to present the Commissions testimony at the October 9, 2002 hearing regarding "Examining Issues Related to Competition in the Pharmaceutical Marketplace: A Review of the FTC Report, 'Generic Drug Entry Prior to Patent Expiration'" before the Health Subcommittee of the House Energy and Commerce Committee. Enclosed please find my written responses to the follow-up questions submitted by Subcommittee members.

Please let me know if I can be of further assistance.

Sincerely,

TIMOTHY J. MURIS
Chairman

Enclosure

cc: The Honorable Sherrod Brown
The Honorable Henry Waxman

QUESTIONS FROM CHAIRMAN BILIRAKIS TO CHAIRMAN MURIS

Question 1) In your testimony you state that some have attempted to "game" the system. Do both brand and generic manufacturers attempt to "game" the system? Further, how prevalent is such "gaming" with respect to the total number of abbreviated new drug applications which have been filed since passage of the Hatch-Waxman Act?

Answer: The FTC Report noted that pharmaceutical manufacturers have attempted to "game" the system in two ways. First, both brand-name and generic manufacturers have entered into agreements that the Commission has alleged to be anticompetitive. The FTC Report indicated that brand-name manufacturers and the first generic applicants had entered into such final agreements for 14 brand-name drug products that had the potential to be anticompetitive because the agreement could delay FDA approval of subsequent eligible generic applicants.

In other instances, brand-name companies have listed patents in the Orange Book that raise questions as to whether they should in fact have been listed. The FTC Report detailed 8 drug products for which this occurred and that triggered additional 30-month stays of FDA approval of generic applicants' abbreviated new drug applications (ANDAs).

The FTC Report examined generic competition for those brand-name drug products (1) subject to an ANDA notice containing a paragraph IV certification;¹ and (2) that brand-name companies received after January 1, 1992 and prior to January 1, 2001. According to the FDA, 8,019 ANDAs were filed with the FDA from the time Hatch-Waxman became effective in 1984 through December 31, 2000. Of these applications, 7,536 (94 percent) raised no patent issues. A substantial portion of the total number of ANDAs, however, relate to the same brand-name drug product or new drug application (NDA). Thus, the total number of ANDAs does not represent 8,019 unique brand-name drug products, and it is unclear as to how many unique brand-name drug products the total 8,019 relate.

Four hundred eighty-three (483) (or 6 percent of the total number of ANDAs filed) contained paragraph IV certifications. The 483 ANDAs related to 130 brand-name drug products as measured by unique NDAs. The FTC Report examined 104 drug products, which had ANDAs filed between 1992 and 2000, out of the 130 total from 1984 to 2000.

Question 2) Did the FTC ever consider restricting pharmaceutical patent rights, which some of our witnesses today will advocate? Does the FTC support limiting any manufacturer's patent rights?

Answer: The Commission did not consider or take a position on the issue of limiting pharmaceutical patent rights. It did examine whether there had been abuse of the "30-month stay provision" of the Hatch-Waxman Act, in order to make recommendations designed to eliminate any such abuse. The Commission recommended permitting only one automatic 30-month stay per drug product per ANDA to resolve infringement disputes over patents listed in the Orange Book prior to the filing date of the generic applicant's ANDA. Thus, the recommendation was tailored to mitigate the possibility of continued abuse of Hatch-Waxman that may deter market entry of more generic drugs.

Question 3) You recommend only one 30-month stay per drug. You also recommend that the 30-month stay should apply to all patents listed at the time of the abbreviated new drug application (ANDA) submission. Others support one 30-month stay applicable to all patents listed at the time of the brand drug's approval. Why is it better to have the 30-month stay apply to drugs listed at time of ANDA submission?

Answer: The FTC Report did not examine whether the 30-month stay should apply to patents listed at the time of the brand-name drug's approval. Rather, the harm that the FTC Report addressed and recommended remedying was the use of 30-month stays for patents listed in the Orange Book after a generic applicant had filed an ANDA for a particular drug product. The FTC Report revealed 8 drug products (out of 104 in the study) for which the brand-name company listed a patent in the Orange Book after the first generic applicant had filed its ANDA.² In these cases, the brand-name company obtained one or more additional 30-month stays of FDA approval of an ANDA for that particular drug product. The 30-month stays caused by the filing of later-issued patents are problematic because they delay FDA approval beyond the average time necessary for ANDA approval. Moreover, in nearly all cases, there are significant questions about whether the patents causing these additional 30-month stays fall within Hatch-Waxman's requirements for Orange Book listings.³ Four courts that have ruled so far on the patents causing more than one 30-month stay have each found the relevant patent to be invalid or not infringed.

Subsequent to the release of the FTC Report, FTC staff examined patents listed in the Orange Book between approval of the NDA and the filing of the first ANDA for that particular drug product. The staff found 23 drug products in which the brand-name company sued the first generic applicant for patent infringement only for patents listed in the Orange Book after NDA approval and before filing of the ANDA. The patents for these 23 products do not appear to raise the same issues of whether they claim the approved drug product or otherwise should be listed in the Orange Book as do the patents for the 8 drug products where the patent was listed after the ANDA had been filed. It is unknown whether these 23 patents could have been obtained from the Patent and Trademark Office (PTO) early enough to

¹ A paragraph IV certification means a certification that a patent listed in the FDA's Orange Book is invalid or will not be infringed by the generic drug for which the ANDA applicant seeks approval.

² This total does not include instances in which the brand-name company initiated suit on a different strength of the same drug product.

³ These questions are discussed in Appendices G and H of the FTC Report.

have been listed in the Orange Book simultaneously with approval of the NDA.⁴ If the brand-name companies could have obtained these patents earlier from the PTO, arguably there is no difference between the two proposals.

Question 4) Right now, to qualify for the 180-day exclusivity period, all a generic manufacturer need do is to be the first to challenge the patent. The manufacturer need not be sued. Do you think that the 180-day exclusivity should be available only to those manufacturers who successfully defend patent suits?

Answer: I am not in a position to answer that question right now. The Commission did not reexamine the policy basis for the 180-day exclusivity provision, nor does it have the facts necessary, to determine whether only those generic manufacturers who successfully defend patent suits should be entitled to the 180-day exclusivity. Rather, the FTC Report examined whether the current 180-day provision had been abused, given the initial balance Congress struck between creating incentives for continued innovation and streamlining the generic drug approval process. Nonetheless, the FTC Report indicated that when a first generic applicant was not sued and received FDA approval, it began commercial marketing in a timely manner that triggered the running of the 180 days and allowed FDA approval of any subsequent eligible generic applicant once the 180 days had run.

Question 5) The 180-day exclusivity can be gamed if a generic manufacturer “parks”, i.e. does not use, the exclusivity. In cases where a manufacturer “parks” the exclusivity, should the manufacturer forfeit it?

Answer: The FTC Report did not address whether manufacturers should necessarily forfeit exclusivity should they enter into an agreement that results in a manufacturer “parking” the exclusivity. Rather, the Report examined whether pharmaceutical manufacturers were abusing the current 180-day provision, given the initial balance Congress struck between creating incentives for continued innovation and streamlining the generic drug approval process. The FTC Report noted that 14 of the 20 final settlement agreements obtained through the study had the potential at the time they were executed to “park” the 180-day exclusivity for some period of time. Nonetheless, agreements that “park” exclusivity may be procompetitive, competitively neutral, or anticompetitive. Thus, the Commission sought notification of these agreements to allow the agency to challenge agreements that adversely affect pharmaceutical competition. To this end, the FTC Report recommended that pharmaceutical manufacturers provide copies of certain agreements to the FTC that may affect, among other things, when the 180-day exclusivity is triggered.

Question 6) When is a settlement in which a brand pays a generic money legitimate, and when is it anti-competitive? What factors guides the FTC in drawing this distinction?

Answer: While the Commission has not attempted to set forth a comprehensive list of potentially objectionable settlement provisions, it is possible to identify from the Commission’s reported cases a few types of provisions that, within the Hatch-Waxman context, have drawn antitrust scrutiny. These include:

- *Provisions that provide for “brand” payments.* “Brand” payments (i.e., payments from the patent holder to the alleged infringer) may merit antitrust scrutiny, because they may represent an anticompetitive division of monopoly profits.
- *Provisions that restrict the generic’s ability to enter with non-infringing products.* Such provisions can extend the boundaries of the patent monopoly without providing any additional public disclosure or incentive to innovate, and therefore have the potential to violate the antitrust laws.
- *Provisions that restrict the generic’s ability to assign or waive its 180-day marketing exclusivity rights.* Because a second ANDA filer may not enter the market until the first filer’s 180-day period of marketing exclusivity has expired, restrictions on assignment or waiver of the exclusivity period can function as a bottleneck, potentially delaying subsequent generic entry for an extended period.

Question 7) Since the FTC began bringing enforcement actions against brands and generics for collusive settlements, has this activity diminished?

Answer: The FTC Report indicated that no interim patent litigation settlement agreements similar to the ones that the Commission had challenged were executed between April 1999 (shortly after the investigations in this area became public) and the end of the period covered by the Study.

Question 8) In your report, you note 8 drugs for which multiple 30-month stays were acquired, and in your testimony you recount two FTC enforcement actions. Why isn’t FTC enforcement action enough to address this problem?

⁴For 6 of these 23 drug products, the patent was issued prior to FDA approval of the NDA, but the brand-name company did not list the patent in the Orange Book until after 30 days after the NDA was approved, although it could have filed it earlier.

Answer: Certainly vigorous enforcement of the antitrust laws in the pharmaceutical area is one of the Commission's priorities, and the Commission will continue its aggressive law enforcement activities. I cannot guarantee that all potential antitrust violations in connection with Hatch-Waxman will come to the agency's attention. Based on the evidence of abuse of Hatch-Waxman that the Commission analyzed in its study, the Commission made two main recommendations to restore the balance that Hatch-Waxman struck between encouraging innovation and providing for a streamlined generic drug approval process. I believe that these recommendations are an efficient and cost-effective means to address the problems documented in the FTC Report.

Question 9) Which occurs more frequently: Anti-competitive agreements by brands and generics, or anti-competitive agreements by generics and generics?

Answer: The FTC Report did not characterize the competitive or anticompetitive nature of the agreements found between brands and generics or between generics and generics. The FTC Report indicated that, among the 104 drug products included in the study, there were settlement agreements between brands and the first generic applicant for 20 different drug products and there were agreements between generic firms for 6 different drug products.

Question 10) You note that in 28% of cases where generics seek approval of patented drugs, the brand company does not invoke the 30-month stay by filing suit in a timely manner. Are there instances in these cases where the brand later sues the generic for infringement?

Answer: Of the drug products where the brand-name company did not sue the first generic company (29 drug products out of 104 drug products included in the Study), there was no evidence that the brand-name company later sued the generic manufacturer of the particular drug product for patent infringement.

Question 11) On page 20 of the FTC report, the Commission states that recent empirical evidence suggests that the rate at which drug patents are found to be invalid is "not out of line with that of patents generally." Can you explain how the FTC reached this conclusion? Doesn't this tend to undermine the claims that brand-name manufacturers are filing frivolous patents? Doesn't it tend to support the brand-name industry's claim that later listed patents represent important incremental innovation?

Answer: The Commission examined the recent empirical literature regarding the rate at which courts find patents invalid.⁵ The FTC Report compared the invalidity rate found in data with that found in broader populations and it showed, as indicated in the FTC Report, that the invalidity rates are similar. The patent invalidity rates found in the broader empirical studies ranged between 27 and 36 percent. The Commission found the invalidity rate of the patents involved in the study to be 28 percent. Thus, the Commission concluded that the invalidity rate is "not out of line with that of patents generally."⁶ The Commission did not obtain information to determine whether the patents claiming the drug products in the study that were not invalidated were "frivolous" or "represent important incremental innovation."

Question 12) S. 812 would bar innovators from suing to enforce patents not listed in the Orange Book by certain deadlines. This isn't something the FTC recommended in its report, is it? Also, under S. 812 an innovator would have to sue within 45 days of ANDA notice in order to enforce its patent, or it would lose all future rights to sue. That isn't something the FTC recommended, is it? Further, S. 812 would create rolling eligibility for the award of 180 day exclusivity. That's not something the FTC recommended, is it? What about limiting 30-month stays to certain kinds of patents? What about creating a private right of action for delisting patents?

Answer: The Commission in the FTC Report did not take a position on S. 812. Rather, the Study examined whether certain provisions of Hatch-Waxman have been subject to abuse that can delay generic entry given the framework initially established by the Amendments. The Study indicated the potential for ongoing problems with respect to two provisions—30-month stay and 180-day exclusivity. The Commission in its Report, therefore, recommended changes to those two provisions to restore the balance that Hatch-Waxman initially struck between encouraging innovation and providing for a streamlined generic drug approval process.

⁵See, e.g., Kimberly A. Moore, *Judges, Juries & Patent Cases: An Empirical Peek Inside the Black Box*, 98 Mich. L. Rev. 365 (2000); John R. Allison, Mark Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA L.Q. 185 (1998).

⁶In some regards, the comparison may not be comparable, as noted in the FTC Report. The invalidity rate calculated in the FTC Report may be understated because patent validity may not have been determined in the cases when there was a decision of non-infringement or in cases when the brand-name company abandoned the litigation.

The Commission observed, however, that the FDA does not review the propriety of patents listed in the Orange Book, and courts have ruled that generic applicants have no private right of action to challenge those listings. The lack of any mechanism to challenge a listing may have real world consequences in that the Commission is aware of a few instances in which a 30-month stay was generated solely by patents in which the propriety of the Orange Book listing was questionable. To address this situation, the Commission suggested that the FDA may want to clarify its listing regulations along the lines the FTC Report suggested. It also recommended that Congress consider enacting a private right to counterclaim and raise the issue of whether the patent properly claims the brand-name product; this may eliminate the delay that the 30-month stay could be causing for improperly listed patents in the Orange Book.

Question 13) Several provisions of the Senate-passed bill would limit brand-name drug patent holders from suing to enforce their patents. In your July 2002 report you suggest that Congress consider overturning *Allergan Inc. v. Alcon Labs, Inc.* in order to ensure brand-name manufacturers access to courts. This is a key distinction between the Senate bill and the FTC approach—could you explain how and why the FTC thought it is important for patent holders to have the rights to enforce those patents?

Answer: The Commission concluded that overruling the holding in the *Allergan* case (which questions the rights of brand-name companies to sue for patent infringement regarding patents obtained or listed after an ANDA with a paragraph IV certification has been filed) is necessary to ensure access to the courts and to encourage the resolution of any patent disputes prior to the beginning of commercial marketing of the drug product. Simultaneous resolution of patent infringement suits with FDA approval time of the ANDA will redound to the benefit of consumers by resolving any possible uncertainty that prevents a generic applicant from marketing its products.

QUESTIONS FROM REPRESENTATIVE WAXMAN TO CHAIRMAN MURIS

Question 1) The report suggests that the 180-day exclusivity period has not been a significant barrier to market entry of 2nd and 3rd generic applicants. Please provide the information on which you based this conclusion.

Answer: The data suggest that if the first generic applicant is sued for patent infringement by the brand-name company, the generic applicant begins commercial marketing only after it has some measure of certainty that its generic product does not infringe the brand-name drug's patents (*i.e.*, it obtains a court decision of non-infringement or patent invalidity). Once it receives such certainty, it begins commercial marketing, which triggers the 180-day exclusivity period. Thus, the 180-day exclusivity by itself does not act as a significant barrier to market entry by 2nd and 3rd generic applicants beyond the 180-day period. The FTC Report indicated, however, that the resolution of patent infringement litigation over 14 drug products (out of a total of 53 drug products) involved an agreement in which the brand-name company and the generic applicant agreed to "park" the first generic applicant's 180-day exclusivity for some period of time, thus potentially delaying FDA approval of subsequent eligible generic applicants. The FTC Report indicated that agreements to "park" the 180-day exclusivity are not necessarily anticompetitive, but can be pro-competitive or competitively neutral. Moreover, the Report indicated that when the first generic applicant is not sued, it begins commercial marketing in a timely manner after receiving FDA approval.

Question 2) Please provide any information you have developed, either before or after the report was issued, on the number and types of patents that have been filed with FDA between approval of an NDA and submission of the first ANDA for that drug. In describing the types of patents, please provide as much detail as possible, including (a) when the patent was filed with the PTO; (b) whether the patent claims the drug substance, a method of using the drug, a formulation of the drug, a process for making the drug, or some other feature of the drug; (c) whether the patent appears to claim the approved drug; (d) to the extent the patent appears to claim the approved drug, any information on the significance of the claimed innovation to the therapeutic value of the drug; and (e) whether they are reasons for or against protecting these patents with 30-month stays.

Answer: Out of the total 75 drug products in the FTC Report where the brand-name company sued the first generic applicant based on patents listed in the Orange Book, brand-name drug companies listed patents in the Orange Book between NDA approval and submission of the first ANDA for 34 drug products.

Of the 34 products in which the brand-name company listed a patent during this period, for 11 products, the generic applicants filed ANDAs with paragraph IV cer-

tifications for patents both listed within 30 days of NDA approval *and* listed after 30 days following NDA approval. Thus, in each of these 11 instances, the 30-month stay that issued was based both on patents filed within 30 days of NDA approval and patents filed after 30 days of NDA approval.

For the remaining 23 drug products, the patents listed during this period were the only patents over which the brand-name company sued the generic applicant, and thus obtained a 30-month stay of FDA approval of the ANDA.⁷ The patents for these 23 products do not appear to raise the same issues about whether they are appropriately listed in the Orange Book as those described in Appendices G and H of the FTC Report. None of the patents for these 23 products were applied for after the NDA had been approved. All except one of the patents were formulation patents; the exception was a drug substance patent. The FTC Report did not examine the significance of the claimed innovations in these patents to the therapeutic value of the drug.

Question 3) Your report focuses on the best way to avoid market abuses of today and tomorrow. Is it not true that if the 30-month stay were eliminated altogether, or were limited to products filed at the time of new drug application, that it would more effectively limit, if not altogether stop these abuses?

Answer: The FTC Report did not reveal what would happen in the absence of the 30-month stay. It appears as though the 30-month stay has been a motivating factor for brand-name companies to file suit within 45 days of being notified that an ANDA has been filed for one of its drug products. The FTC Report showed that both brand-name and generic companies assumed that, if patent litigation were to occur, it would be filed within 45 days of the ANDA filing in order for the brand-name company to obtain the 30-month stay. Generic applicants who were not sued during that time frame proceeded to commercial marketing without significant delays and, at least for the drug products included in the study, were not sued for patent infringement once commercial marketing had begun.

Question 4) Almost a year and a half ago, you filed a citizen petition to the FDA to determine whether various patents were listed for anti-competitive reasons. To date, you have not received a response. Please describe the importance of your requests to the interests of consumers and a competitive marketplace.

Answer: The FDA recently has released a Notice of Proposed Rulemaking that addresses many of the issues raised by the FTC Citizen Petition. The FTC is in the process of studying the FDA's proposals and plans to provide a comment to the FDA. The listing of patents in the Orange Book can affect the timing of FDA approval of generic drug products. Thus, it is critical to ensure that the patents in the Orange Book are appropriately listed.

RESPONSE FOR THE RECORD OF SHARON LEVINE, ASSOCIATE EXECUTIVE DIRECTOR,
THE PERMANENTE MEDICAL GROUP, INC.

Question 1: You state in your testimony that you are “unaware of a single industry besides the brand-name pharmaceutical industry that has the ability to extend unilaterally and automatically protection against competition.” Are you aware of any other industry which has their patents infringed by competitors, as is allowed under the “Bolar Amendment”?

Response: In *Eli Lilly & Co. v. Medtronic, Inc.* (496 U.S. 661 (1990)), the Supreme Court, in an opinion by Justice Scalia, found that the Bolar Amendment was intended to work in tandem with the patent term restoration provisions of Hatch-Waxman to respond to “two unintended distortions” in the patent law. The patent term restoration provisions address the fact that a patent holder cannot reap profits during the early years of the patent term prior to obtaining FDA marketing approval. Likewise, the Bolar Amendment assures that the patent holders do not enjoy a de facto patent term extension during the period after expiration but prior to a generic company obtaining FDA marketing approval for a generic product. Thus the patent term restoration provisions and the Bolar Amendment are essentially two sides of the same coin.

The Supreme Court held in *Medtronic* that the Bolar Amendment applies to all of the products eligible for a patent term extension under the Hatch-Waxman Act, including medical devices, food additives, color additives, new drugs, antibiotic drugs, and human biological products.

⁷ For 6 of these 23 drug products, the patent was issue prior to FDA approval of the NDA, but the brand-name company did not list the patent in the Orange Book until after 30 days after the NDA was approved, although it could have filed it earlier.

Moreover, it is important to understand that the Bolar Amendment does not permit patent infringement. The Bolar Amendment is merely a mechanism by which generic companies may begin research and development, and other activities necessary for Food and Drug Administration (FDA) approval of a generic drug product prior to the expiration of a patent on a brand-name product. In fact, the Bolar Amendment specifically provides that such activities “shall not be an act of patent infringement.”

Question 2: Generic manufacturers can earn 180 days of exclusivity for being the first to challenge a brand patent, without having to successfully defend suit. Of course, for many larger drugs, ten to twelve generic manufacturers file ANDAs with paragraph IV certifications, irrespective of exclusivity. Wouldn't repeal of this exclusivity save insurers money in the long run?

Response: The landmark Hatch-Waxman Act recognized that the process of patenting pharmaceutical products represents the opportunity for patents to be granted that may unjustly prevent generic competition. To further the public policy goal of improving consumer access to affordable generic drugs, the Hatch-Waxman Act provided an incentive for generic companies to challenge these suspect patents. It provides 180-days of generic market exclusivity to allow the generic company to recover some of the costs associated with the patent challenge process.

The 180-day exclusivity period provides a useful economic incentive to encourage the patent challenge process. The patent challenge process reduces health care costs, when successful, by permitting the introduction of generic competition years earlier than otherwise would have been possible. The exclusivity is the generic company's reward for removing questionable patents that act as barriers to consumer's access to affordable drug products. The competition that follows a successful patent challenge can generate billions of dollars in savings for the consumer.

For example, the successful challenge of the patent for the anti-depressant drug Prozac (generically fluoxetine) eventually resulted in a wholesale price reduction for fluoxetine therapy from \$2.65 to \$0.10 for a daily dose of the drug. That this pricing did not occur immediately when generic Prozac first became available partly validates your question about whether the 180-day exclusivity provision delays the establishment of such commodity market prices.

However, your question is only part of a more complex and important one: Does the 180-day exclusivity provision delay commodity market pricing on a generic drug to a point in time beyond which such pricing on the drug would have been available without 180-day exclusivity? On this point, I have no information suggesting that without the 180-day exclusivity incentive payers like employers, insurers and consumers would be better off. It is my own view that the 180-day provision more likely increases competition sooner than would otherwise be the case, resulting in lower drug prices, more consumer choice, and greater savings to all aspects of the U.S. economy.

Patent rights are a vital incentive for innovation, and therefore deserve protection. The 180-day exclusivity provision probably represents a useful check and balance to assure that only the owners of worthy patents are rewarded, and questionable patents are not permitted to deny or delay Americans' access to affordable prescription drugs.

RESPONSE FOR THE RECORD OF GREGORY J. GLOVER, ON BEHALF OF
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

Hatch-Waxman's Unique Limitations on Brand-name Drug Patents

This answer responds to the Honorable Michael Bilirakis' Question 3, and the Honorable Ralph M. Hall's question regarding "Patent law applicable to the pharmaceutical sector."

I hear generics constantly say they want brand patents to be treated just like all other patents during patent litigation. Aren't brand patents treated differently prior to litigation however? Could you please explain the benefit of the "Bolar Amendment" to the generic industry?

The generic industry has argued that the patent laws applicable in the pharmaceutical sector are more innovator-friendly than those applicable in other sectors of the economy. What is the research-based pharmaceutical industry's response to this?

Brand-name drug patents are treated very differently from other patents. Ordinarily, upon issuance, patents are presumed to be valid and enforceable. See 35 U.S.C. § 182. Under the Patent Act, the holder of a patent has the right to exclude others from making, using, selling, or offering to sell the patented invention during the term of the patent, which is 20 years from the date on which the patent applica-

tion is filed. *Id.* § 156. The right is absolute and anyone who, without authority, makes, uses, sells, or offers to sell a patented invention during the term of the patent is an infringer of the patent. The patent holder can obtain an injunction prohibiting the infringing activity, and recover up to three times its damages caused by the infringing acts.

Hatch-Waxman limited pharmaceutical patent rights by immunizing generic drug manufacturers from suits for infringement based on their manufacture and use of patented drugs for purposes of seeking FDA approval to market a generic copy. In this special exception to patent law, Hatch-Waxman permits a generic drug company to manufacture and use the brand-name drug to obtain bioequivalence data for its FDA application, so that it can be approved for marketing immediately upon patent expiration. Ordinarily under patent law, manufacturing a patented product—whether or not during the research and development phase for a competing product—constitutes patent infringement. Hatch-Waxman overruled *Roche Inc. v. Bolar Pharms. Co., Inc.*, 733 F.2d 858 (Fed. Cir. 1984), where the Federal Circuit had found patent infringement based on a generic company's use of a patented drug in testing for purposes of seeking FDA approval.

Before generic pharmaceutical manufacturers were granted these preferences, they controlled only 19 percent of the prescription drug market share and roughly only 1 out of 3 top-selling innovator drugs with no unexpired patents had generic competition. Today, the generic share of the market is nearly 50 percent and every top-selling drug subject to Hatch-Waxman whose patents have expired can expect generic competition.

Effective Patent Life for brand name products

This response answers the Honorable Edolphus Towns question relating to "Patent Life."

Can you explain the concept of "effective patent life"? How does this 14-year term compare with the patents available in other industries?

The patent term is 20 years from the date an application is filed with the Patent and Trademark Office. Because it takes between 10 to 15 years on average to develop a drug—from the earliest stages of discovery to final FDA approval—significant portions of a prescription drug's patent life are used up before the product even enters the market.

Effective Patent Life (EPL) refers to the amount of time a product is on the market before patent(s) covering it expire. Research by Henry Grabowski and John Vernon at Duke University places the EPL on prescription drugs at 11-12 years. Estimates by the American Intellectual Property Law Association quote the EPL for products other than pharmaceuticals at 18.5 years.

Under Hatch-Waxman, an innovator may be granted patent term restoration for time lost during the regulatory review process. Innovators may receive one-half day restoration for each day of clinical trials, and day-for-day restoration for time lost during FDA review of a drug application. The total amount of restoration may not exceed five years, and the effective patent life of the drug may not exceed 14 years.

Use of 30-Month Stays

This answer responds to the Honorable Michael Bilirakis' Questions 1, 2, 4, 5, and 10, the Honorable Ralph M. Hall's questions regarding "Late listing of patents" and "Time of patent listing," and the Honorable Edolphus Towns' question regarding "Frivolous listings."

1) Could you please explain for the Committee instances where a brand should be allowed to invoke multiple 30-month stays. In other words, when can you both innovate enough to get a patent, but not enough so that you can still claim the approved drug?

2) GPhA has argued that the prospect of receiving the initial 30-month stay, combined with FDA's policy of permitting successive 30-month stays, provides brand name manufacturers with an enormous incentive to submit patents for listing in the Orange Book, even if they do not satisfy the listing criteria contained in the Hatch Waxman Act. Do you agree? What is PhRMA's response?

4) Why do brand manufacturers file so many patents per drug now? Wasn't it the case that when Hatch-Waxman was passed, most drugs had one or two patents? Why are there, sometimes, ten patents per drug now?

5) You state in your testimony that the FTC focused on 8 examples of abuse, and that in 99.9% of the cases there are not multiple 30-month stays. Isn't true, however, that multiple 30-month stays are a recent trend, and that without reform we might expect more examples in the future?

10) In your statement, you quote the Patent and Trademark Office, where they state that S.812 "would likely to the opposite of what its title suggests—

by limiting access to cutting-edge drugs, decreasing innovation, and ultimately harming the quality of treatments available to patients.” Precisely what in S.812 would harm patients?

Can you explain for us why a brand-name pharmaceutical company might need to list a patent in the Orange Book significantly after NDA approval? Why is this practice, and the subsequent litigation resulting in additional 30-month stays, not an abuse of the Hatch-Waxman Act?

One of the key differences between the FTC Report and the Senate-passed bill, one of the issues that people have been focusing on, is this question of when patents must be listed, in order to be eligible for a 30-month stay. The FTC report recommends that stays be limited to patents listed when the ANDA is filed. S.812 recommends that stays be limited to patents listed within 30 days of NDA approval. Can you shed some light on the importance of this issue? What does it matter which cutoff date Congress picks? What is the significance of the cutoff date?

GPhA has argued that the prospect of receiving the initial 30-month stay, combined with FDA’s policy of permitting successive 30-month stays, provides brand name manufacturers with an enormous incentive to submit patents for listing in the Orange Book, even if they do not satisfy the listing criteria contained in the Hatch Waxman Act. What is PhRMA’s response?

The 30-month stay allows for the resolution of patent disputes before a generic manufacturer enters the market with a potentially infringing product. Hatch-Waxman stripped innovators of their right to sue before a generic manufacturer submits an application for approval to FDA, although that generic manufacturer has performed acts that, in other industries, would amount to patent infringement. The statute therefore created the 30-month stay to permit the innovator to enforce its patent rights by bringing a suit for infringement before the generic product receives approval for marketing. The stay does not extend the term of a patent and is initiated only in response to an innovator’s filing suit to enforce an un-expired patent.

When a generic manufacturer seeks approval to enter the market before all patents on the innovator product expire, it must file a so-called “paragraph IV” certification to each patent listed in the Orange Book. The generic applicant must certify to all patents listed at the same time. If the innovator exercises its right to file a paragraph IV lawsuit under the Hatch-Waxman Act, each patent generates a 30-month stay, but these stays run concurrently. In rare instances, however, patents covering the innovator product may issue and be listed in the Orange Book *after* the ANDA is filed. These cases are uncommon, but they may lead to non-concurrent 30-month stays. This could be the case, for example, if a patent was filed with the PTO for improvements that allow manufacturing of the drug without production of an impurity that presents toxicity risks. This would likely be filed well after the original patents, and—depending on the speed with which it was reviewed at PTO—could issue from PTO and be listed in the Orange Book well after NDA approval or even ANDA submission. If an ANDA applicant amended its ANDA to include this innovation and patent and the patent owner sued within 45 days of notice, there would be a new non-concurrent stay of up to 30 months. As PTO explained in a July 30 letter to Senator Hatch, “the timing of issuance bears no relation to the importance of innovation.”

Contrary to assertions by others, there is no evidence that the 30-month stay provides an incentive to list inappropriate patents. That several patents may be listed for a single drug is not unusual in other types of commercial products: multiple patents simply reflect years of complex research and multiple innovations, many of which are patentable under standards as set forth in patent law and enforced by the Patent and Trademark Office.

In fact, the July 2002 Federal Trade Commission study found only eight instances since 1992 in which an innovator obtained a second 30-month stay. There is no evidence that this will become more common in the future, though the trend of generic manufacturers filing ANDAs earlier and earlier in the life of an approved new drug could provide a justified reason for maintaining the availability of non-concurrent stays.

S.812, a bill passed by the Senate on July 30 that contains multiple revisions to the Hatch-Waxman Act, would treat patents differently depending on their issuance date. S.812 would apply a 30-month stay only to patents that issue from PTO within 30 days of the new drug application approval.¹ As PTO points out, this limitation is “arbitrary and unrealistic” because “the timing of issuance bears no relation to

¹ Alternatively, the FTC report suggests the denial of a 30-month stay to any patent listed after the relevant ANDA was filed.

the importance of innovation” and because “the patent applicant often has no control over when a patent issues.”

I also note one recent regulatory development: The FDA has issued a proposed rule that would change its current interpretation of allowing multiple 30-month stay provisions for each ANDA to allowing only one 30-month stay for each ANDA. An ANDA applicant would not have to provide notice that it had made a paragraph IV certification challenging the validity or infringement of a listed patent if the paragraph IV certification was added as an amendment to the ANDA and the application already contained a paragraph IV certification to another patent. Although the ANDA applicant would have to make a new certification, it would not need to provide notice under the statute, eliminating the ability of the innovator to seek a 30-month stay in which to litigate the patent. The innovator would retain its right to obtain a preliminary injunction from a court to prevent the ANDA applicant from entering the market.

At bottom, limitations on the 30-month stay are based on the incorrect assumption that innovation stops when the innovator has an approved version of its product. The reality is that pioneer companies do not stop innovating once the first patent has been applied for at the PTO, or once the product approval process begins at the FDA. Instead, innovation continues in order to improve a drug’s side effect profile, to improve its stability, to enhance the efficiency of its delivery, to improve its dosing regimens, and to develop changes in dosage forms.

A legislative framework that deprives patent owners of their core rights, and that arbitrarily and irrationally deprives innovators of the benefit of their innovation, will not provide the incentives necessary for further research and development, and will result in fewer new medicines for U.S. patients.

Use of Proposed 45-day Provision to Cut Off All Patent Enforcement Rights

This answer responds to the Honorable Michael Bilirakis’ Question 6 and further responds to Question 10.

6) Some would propose limiting brand patent rights if a brand company does not sue within 45 days. What impact would this have on innovation?

10) In your statement, you quote the Patent and Trademark Office, where they state that S.812 “would likely to the opposite of what its title suggests—by limiting access to cutting-edge drugs, decreasing innovation, and ultimately harming the quality of treatments available to patients.” Precisely what in S.812 would harm patients?

S. 812 currently provides that when a generic drug manufacturer files an application with FDA stating its intent to market a copy of an innovator drug before relevant patents on that drug expire, the patent holder has 45 days to file a lawsuit to enforce its patent. If the innovator does not bring a patent infringement suit within 45 days, all rights to sue for future enforcement of that patent would be forfeited. Though the Hatch-Waxman Act mandates that the patent holder sue within 45 days of notice of a paragraph IV certification in order to obtain the benefit of the 30-month stay provision, the patent holder may always seek patent enforcement remedies either against other generic applicants or outside the context of the Hatch-Waxman Act. S.812 would foreclose those options if the pioneer did not sue within 45 days.

It is well established law that a patent is a property right. By diminishing the core right of a patent holder—the right to sue to prevent infringement by others—the government would be infringing a fundamental right. The courts have found this is equivalent to the total occupation of a piece of real property, which is unconstitutional. Further, the harm from this sort of taking is irreparable. The ability to enforce a patent on pharmaceutical innovation is one of the major incentives for research and development. An arbitrary deadline for suit after which all property rights in the patent would be forfeited would function as a significant disincentive to innovate in the first instance.

180-day Generic Exclusivity (Questions 7, 8)

This response answers the Honorable Michael Bilirakis’ Questions 7 and 8.

7) Does the 180-day generic exclusivity make sense in cases where multiple generic applicants are lined up to challenge the patent?

8) Does the 180-day exclusivity make more economic sense to society when a patent is invalidated, rather than in instances where a generic finds a way to innovate around the patent?

The operation of the 180-day Generic Drug Exclusivity Provision has been primarily a question for the generic industry, FDA, and Congress. Nevertheless, the circumstances that led to enactment of the 180-day exclusivity provision have changed significantly since 1984. The exclusivity provision was intended to provide

an incentive to generic manufacturers to challenge listed patents. It operates by shielding the first generic from competition with other generic companies, even if they are ready, willing, and able to enter the market. Today, however, there is no shortage of generic companies willing to challenge patents and file ANDAs. Since 1984, the generic share of the prescription drug market has grown to nearly 50 percent. Senator Hatch has recently suggested that it might be timely to assess the continuing need for and utility of such an incentive.

Support for Statement that “the increased availability and use of innovative medicines is a true driver of reduced overall healthcare costs.”

This response answers the Honorable Michael Bilirakis’ Question 9.

In your statement, you state “the increased availability and use of innovative medicines is a true driver of reduced overall healthcare costs.” What proof do you have to back up this statement?

Despite the attention paid to increases prescription drug spending, medicines remain the smallest portion of the health care dollar. According to National Health Care Expenditure data, prescription drugs accounted for 9 percent of health care spending in 2000, while hospital care amounted to 32 percent and physician services were 22%.²

The economic and medical literature is replete with studies demonstrating reductions in health care spending resulting from increased use of pharmaceuticals. For example:

- Recent work by Columbia University Professor Frank Lichtenberg demonstrated that each additional dollar spent on replacing older medicines with newer ones reduces total health care spending by \$6.17.³
- In recent years, breakthrough medicines offered Alzheimer’s patients their first real hope. An estimated 4 million Americans currently have Alzheimer’s disease. By 2030, that number is projected to increase to as many as 9 million. Currently, the direct and indirect cost of caring for people with Alzheimer’s is \$100 billion nationally.⁴ According to a study published in the March issue of *Managed Care Interface* a four-fold increase in spending on drug therapy for mild to moderate Alzheimer’s disease resulted in a one-third decline in total health costs. For a group of patients taking drugs to treat their Alzheimer’s, drug costs went up by over \$1,000, but hospital costs dropped by \$2,883 and nursing home costs by \$1,842. The result—nearly \$3900 in savings compared to patients not taking Alzheimer’s drugs.⁵
- In research presented at the 12th World AIDS Conference in 1998, the Department of Veterans Affairs found that by giving patients full access to new AIDS drugs it helped realize a savings of \$18 million in AIDS treatment costs in 1997.⁶
- A study which reviewed patient records in the North Carolina Medicaid program for one year before and one year after the introduction of inhaled corticosteroid therapy found that for those patients using the inhaled steroid therapy for asthma, there was a 50 percent decrease in hospitalization rates and a 26 percent decrease in outpatient visits. The comparison group had a 23 percent increase in hospitalization rates and a 36 percent increase in outpatient visits. According to a cost analysis, use of the inhaled corticosteroid therapy reduced total health care costs by 24 percent per asthma patient per month.⁷

Rather than citing pharmaceuticals as the principal source of most health cost increases, it must be recognized that prescription drug spending is small relative to total health care spending and can in fact achieve savings on hospitalization and

²Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group “National Health Care Expenditures,” 17 July 2002, <<http://www.hcfa.gov/stats>> (8 November 2002).

³Frank Lichtenberg, “Benefits and Costs of Newer Drugs: An Update,” NBER Working Paper 8996. Available online 07/23/02: <http://www.nber.org/papers/w8996>.

⁴National Institute on Aging, *Progress Report on Alzheimer’s Disease, 2000: Taking the Next Step*, (Washington, DC: National Institutes of Health, 2001), 3.

⁵Jerold W. Hill, et al., “The effect of donepezil therapy on health costs in a Medicare managed care plan,” *Managed Care Interface* 15 (March 2002): 3, 63-70.

⁶Abid Rahman, et al., “Inversion of Inpatient/Outpatient HIV Service Utilization: Impact of Improved Therapies, Clinician Education and Case Management in the U.S. Department of Veterans Affairs,” AIDS Service Department of Veterans Affairs, International Conference on AIDS, July 1998.

⁷R. Balkrishnan, MS (Pharm), et al., “Outcomes and Cost Benefits Associated With the Introduction of Inhaled Corticosteroid Therapy in a Medicaid Population of Asthmatic Patients,” *Clinical Therapeutics*, Vol. 20, No. 3, 1998.

other medical costs. Pharmaceuticals save lives and increase quality of life while creating offsetting savings on other health services.

Response to the “15 most egregious examples of Hatch-Waxman abuse” (Question 14)

This response answers the Honorable Edolphus Towns’ question regarding “Examples of Hatch Waxman Abuse.”

The generic industry claims that fifteen drugs represent the “15 most egregious examples of Hatch-Waxman abuse.” Do you agree or disagree that these are in fact examples of abuse? And if not, why not?

The generic industry claims that 15 drugs—Neurontin®, Taxol®, Platinol®, Prilosec®, Paxil®, BuSpar®, Tiazac®, Ultram®, Zantac®, Coumadin®, Nicorette®, Temovate®, Wellbutrin®, Questran®, and Glucophage®—represent the “15 most egregious examples of Hatch-Waxman abuse.” The generic industry is simply wrong about the innovator industry’s actions. At bottom, the assertions boil down to complaints about continuing innovation on pioneer drugs and the identification of significant consumer safety and public health issues associated with generic copies of pioneer drugs. I have arranged my response by the issues raised in these examples.

Non-Patent Issues

The Coumadin®, Nicorette®, Temovate®, Questran®, and Glucophage® examples involve various issues of critical importance to the pharmaceutical industry—the public health, the right to petition agencies concerning agency action, bioequivalence, and clarifying unsettled areas of the law. These examples do not relate to the patent scheme of Hatch-Waxman but to the FDA’s exercise of its regulatory authorities.

Patent Infringement Findings

Neurontin®, Zantac®, and Wellbutrin® are examples of patent holders attempting to protect legitimate intellectual property rights. Finding patent infringement is a matter for the courts that frequently involves difficult and complex issues of fact and law. In these cases, the patent holder sought only to enforce its patent rights.

Patent Validity

Platinol® and BuSpar® each involve highly technical disputes on the validity of relevant patents. Under the relevant law patents are presumed valid and can be found invalid only after substantial evidence has been produced to the contrary to the presiding court.

Operation of Hatch-Waxman

The Prilosec® and Ultram® examples demonstrate appropriate operation of the Hatch-Waxman Act’s patent and exclusivity provisions, which provide incentives for continued innovation. There were no non-concurrent 30-month stays at issue in either case.

Use of a 30-month stay

In the Taxol® matter the patent owner sought a single 30-month stay in which to litigate its patent rights.

Realities of Innovation

The Paxil® example makes clear that innovation in the pharmaceutical industry frequently comes long after the issuance of the initial patent. That fact, in combination with earlier filings of ANDAs by generic manufacturers, results in the possibility for multiple patents to cover the additional discoveries made concerning a product. As explained by the PTO in a July 30 letter to Senator Hatch, “the timing of issuance bears no relation to the importance of innovation.”

Manipulation by Generic Manufacturers of Hatch-Waxman

Biovail, a generic drug manufacturer, has been accused of using successive 30-month stays to extend its period of exclusive marketing of Tiazac®. Through litigation and settlement not involving the research-based pharmaceutical companies, generic forms of Tiazac® are now on the market.

Response to request to “provide a complete list of patents that claim an approved drug, were issued by the PTO more than 30 days after NDA approval, and were filed with FDA pursuant to § 3505(c)(2)” and to provide related information.

This response answers the Honorable Henry A. Waxman’s question.

Please provide a complete list of patents that claim an approved drug, were issued by the PTO more than 30 days after NDA approval, and were filed with

FDA pursuant to section 505(c)(2). Be sure to include all such patents that have triggered a 30-month stay of approval. For each such patent, provide the following information:

- (a) the date on which the patent was filed with the PTO;
- (b) the name of the approved drug claimed by the patent, the date of its approval, and the date of first marketing;
- (c) whether the patent was a continuation patent or the subject of a terminal disclaimer, and if so, the original patent whose termination date the new patent also took;
- (d) what innovation the patent claimed;
- (e) the cost of developing that innovation;
- (f) whether that innovation was the subject of an FDA approval, and if so, the date of that approval;
- (g) whether the patent was the subject of litigation and the outcome of the litigation; and
- (h) whether any 30-month stays were imposed pursuant to the filing of a patent infringement suit to enforce the patent;
- (i) whether there was more than one 30-month stay associated with the approved drug claimed by the patent.

PhRMA does not have a list of patents issued by PTO more than 30 days after NDA approval. Furthermore, some of this information that you request—such as the cost of developing the innovation that is the subject of the patent in question—would be viewed as confidential and proprietary by the companies.